HIT Policy Committee's
Meaningful Use & Quality Measures Workgroups and
HIT Standards Committee's
Consumer/Patient Engagement Power Team
Patient Generated Data Hearing
Final Transcript
June 8, 2012

Presentation

Operator

All lines are now bridged.

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good morning everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is the Patient Generated Data hearing, sponsored by the HIT Policy Committee's Meaningful Use Workgroup and Quality Measures Workgroup, as well as the HIT Standards Committee's Consumer Engagement Power Team. This is a public hearing and there will be time for public comment at the end of the agenda. The call is also being transcribed, so please be sure to identify yourself before speaking. I think instead of doing a formal roll, I'll just go around the table and ask everyone to introduce themselves and just state which committee they're on and workgroup they're on. I'll start with Michelle.

Michelle Nelson - Office of the National Coordinator

Michelle Nelson, ONC.

Josh Seidman – Office of the National Coordinator

Josh Seidman, ONC.

H. Westley Clark – Substance Abuse & Mental Health Services Administration

Wes Clark, SAMHSA as well as the Policy Quality Measures Workgroup.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Hi, Amy Zimmerman, the Meaningful Use Workgroup.

Hugo Campos – Patient Advocate

Hugo Campos, the Meaningful Use Workgroup.

Arthur Davidson – Denver Public Health Department – Director

Art Davidson, Denver Health and HIT Policy Committee.

Norma Lang, RN – University of Wisconsin

Norma Lang, University of Wisconsin, Milwaukee and Quality Measure Group.

Tripp Bradd – Skyline Family Practice, VA

Tripp Bradd, Quality Measures Workgroup.

Rebecca Kush – Clinical Data Interchange Standards Consortium – President and CEO

Becky Kush, from CDISC, on the Standards Committee.

Kate Goodrich - Centers for Medicare & Medicaid Services

Kate Goodrich, CMS.

Eva Powell – National Partnership for Women & Families

Eva Powell, the National Partnership for Women and Families, on the Quality Measures Workgroup.

David Lansky – Pacific Business Group on Health – President and CEO

David Lansky, Pacific Business Group on Health, on the Policy Committee.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul Tang, Palo Alto Medical Foundation, Policy Committee.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Leslie Kelly Hall, Healthwise, on the Policy Committee Meaningful Use, the Standards Committee, Patient Engagement Power Team for Standards Committee, Patient Engagement and Care Coordination for Policy Committee, and Privacy and Security for the Policy Committee.

Gayle Harrell – Florida House of Representatives

Gayle Harrell, State Representative from Florida on the Policy Committee and the Tiger Team, Privacy and Security Tiger Team, there's two of them I think.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, Standards has its own. Deven McGraw Policy Committee and the Privacy and Security Tiger Team for the Policy Committee.

Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics

Hi, Liz Johnson, Tenet Healthcare, Standards Committee Implementation Workgroup and Power Team for Patient Engagement.

John Derr – Golden Living, LLC

John Derr, Golden Living, Standards Committee, the Implementation Workgroup and the Patient Engagement and Quality Workgroups.

George Hripcsak – Columbia University

George Hripcsak, Columbia University, the Meaningful Use Workgroup.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf, Kindred Healthcare, Policy Committee Workgroup on Certification Adoption and on, what are we doing, Care Coordination.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Charlene Underwood, Siemens, Meaningful Use Workgroup.

Floyd Eisenberg – National Quality Forum – Senior Vice President of Health Information Technology

Floyd Eisenberg, NQF, Standards Committee.

Russell Leftwich, MD – Tennessee Office of eHealth Initiatives

Russ Leftwich, State of Tennessee, the Patient Engagement Power Team.

MacKenzie Robertson – Office of the National Coordinator

Thank you, and are there any members on the line?

Greg Pace – Social Security Administration

Yes, this is Greg Pace, Social Security Administration, Meaningful Use Workgroup.

Sharon Terry – Genetic Alliance – President and CEO

Sharon Terry, Genetic Alliance, Standards Committee Privacy and Security Workgroup and the Consumer Engagement Power Team.

MacKenzie Robertson – Office of the National Coordinator

Anyone else on the line?

Kate Christensen, MD – Kaiser Permanente

This is Kate Christensen; I'm calling from Kaiser Permanente for Jaime Ferguson.

MacKenzie Robertson – Office of the National Coordinator

Okay, thank you very much. And before I turn it over to Paul to formally open the hearing, I'll just have Josh Seidman give a few opening remarks.

Josh Seidman – Office of the National Coordinator

Great, thanks so much. I'm really excited about this hearing; I think this is something that many people have been talking about. Just for a little bit of context -- the issue of incorporating patient-generated data is something that the Policy Committee started talking about three years ago and it began to lay out the whole vision for the multiple stages of Meaningful Use. Two years ago, in April of 2010, the Meaningful Use Workgroup held a hearing on engaging patients and families, and this was certainly one of the issues that came up. And certainly some of the things that this Committee proposed for Stage 2 begin to get down that road by moving … proposing the movement from the access and copy of information to the view, download and transfer and the idea of secure messaging between patients and providers. All that said, I think that there has been a lot of enthusiasm and expectation around what could happen if there was even more incorporation of patient-generated data, and really just wanted to set a framework of the types that have been discussed by this committee in the past.

So, the first is really around the incorporation of data generated from technologies, things like remote bio-monitoring, people managing chronic conditions at home and wherever they are 24/7. The second is around patient-reported data, things that are around symptoms or health risk assessments, the idea of getting reported data into the EHR as an important data element that can be used for all kinds of things. One of the things that this Committee and these workgroups have talked a lot about is the issue of information reconciliation and the role that patients can play in helping to ensure that the data in the clinical record are accurate, and so that's something that has been discussed.

And then finally, the issue of patient-reported outcomes data, and this has been something that has been a big topic of the Quality Measurement Workgroup in particular. I'm trying to think about really two kinds of patient-reported data that might be important. One is, really, that it's used for accountability, so things like caps or other experience of care instruments, which are being used in things like ACOs, etcetera, to ensure that providers and other organizations are accountable for the experience that patients and families have. But then there's another kind of patient-reported outcomes, which is data that can be used for quality improvement purposes and thinking about the role that that patient-reported quality of care information can be used for ongoing management of conditions -- things like functional status, patient activation, shared decision making or measures of decision quality. All of these things are elements that can be used both for quality measurement, but also for helping to use at the point of care for ongoing care management. So, I just want to provide that context and I will turn it now over to Paul.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Josh. As Josh mentioned, this is a very exciting day. Back in 2009 when we were putting together the framework for Meaningful Use and we brought out category two, which is engage patients and families, that was a momentous occasion and I think we had a placeholder. So today was just a gleam in our eyes back then, and we had a placeholder for this kind of thing, and finally we're putting something in its place. So, this is very exciting, we're working towards Stage 3. If you thing about it, before EHRs, on paper, this wasn't even possible, without a lot of effort of calling around the country, and now, all of a sudden, this can be possible to get directly from patients, and their convenience, from wherever. Even when it was just on the web, you had to carry around a PC to enter it, and now it's available to virtually everybody with a smartphone or some other devices that can get this information in there.

It's also an opportunity to instrument health and not just sickness. So, that's another kind of transformation or paradigm shift. Yet it still has challenges. So we brought together this group in order to one, understand some of the benefits, but two, understand some of the challenges, so that we can start… some of which are potentially amenable to policy changes. And so, our eye is on how can we understand the opportunities, how can we understand the challenges; but how can we, from a policy level, make a difference and make this much more possible. So, that's our goal for today, is to get ideas from the panelists. And fortunately we have Jonathan Wald, from RTI, who's going to first give an overview of a white paper they put together to give us a bit of an environmental scan, and then we'll go into the various panels, starting out with some of the uses of patient-reported information, panel 2 talking about emerging practices because some organizations are starting to take advantage of this.

After lunch we're going to talk about some of the policy issues, some of the questions and some of the things that we need to deal with as a Policy Committee in order to try to remove some of the barriers and potentially even put in some facilitators. And finally completing with some of the challenges. So we'll sort of wrap up a bit at the end of today, and all of this will go into our various workgroups, not only Meaningful Use and Patient Engagement, but also in the Quality Measures. So we're going to take a lot of this input and try to put it into policy recommendations at least. So thank you everyone for participating around the committee and the workgroups, but also from the panelists we're going to hear from today. So let's begin with Jonathan Wald then.

Jonathan Wald, MD, MPH - Director of Patient-Centered Technologies, Center for the Advancement of Health IT, RTI

Great. Thank you Paul. I wanted to start by thanking the committee for inviting me down today to present the findings on the white paper on Patient-generated Health Data, and I'm pleased to represent the RTI team. We prepared this white paper for the Office of the National Coordinator, specifically for the Office of Policy and Planning, and this work was conducted by Michael Shapiro, Doug Johnston, myself and Don Mon, at RTI. And the background is that back in October of 2011, we got a request from the ONC to put together a forward-looking paper, a white paper, on patient-generated data, and really to try to frame the issues. And so we agreed that we would contact experts, we had informal conversations with 19 experts. It turns out four of them are in room today, or on the phone today, which is wonderful. In December we shared some preliminary findings, in February, ONC prepared a listening session at HIMSS to get some more input, and in April, we released the white paper.

And so what I'm going to talk about today -- and the white paper is available as materials for all the members of the committee and publically as well -- so we'll be taking a high level look at a working definition that we used in the white paper for patient-generated health data, talk about data flows, issues that were identified and then some options to consider for the ONC, since one of the goals was for us to sort of gather information and help move the ball forward in thinking about what can be done. The working definition of patient-generated health data is really that it's data – it's health related data of many, many different flavors. It could be health history, symptoms, biometric data, treatment history, lifestyle choices and other things, but the point is that it's created, recorded, gathered or inferred from or by patients to help address a health concern, and the patient-generated health data are distinct from the data that's generated in clinical settings and through encounters with providers in two ways. First, patients, not providers, are primarily responsible for capturing or recording the data and second, patients direct the sharing or the distribution of the data to healthcare providers, to others. They may use it in self-management, for example. So, in these ways patient-generated health data compliments provider-directed capture and flow of health-related data across the health system.

And we put together, and you'll see it in figure 1 in the white paper, and I guess I should be advancing the slides, I'm failing on my job here; let me go ahead and do that. So figure 1 is a picture that illustrates health data flows, and the main elements of the picture are on the left is this area of data capture where people, caregivers, could be patients if they're in that role or status, are somehow contributing information that's getting captured. It could be that they're wearing a sensor and that that data is flowing into something, a laptop that they have locally or even wirelessly to the cloud somewhere. It could be that they're keying information into their smartphone; it could be that they're on a laptop; it could be that they're writing in a log book. So, it's not technology dependent, but there's that step of data capture and once the data is captured, it's in some kind of a data store, and once in a data store, it can be potentially shared.

The second area is labeled as data transfer and that's the flow -- the movement of data from point A to point B -- and it's either under patient direction or it's at least authorized by patients. If it's happening passively, it may be that information was requested by a provider, it may be that this is spontaneously pushed or offered by patients to somebody else. And then the third part of the diagram is the review and document area, and that turns out to be really critical because it's surrounded by a box. And the reason it's surrounded by a box is that the box represents an organization and typically as health data moves into an organization, which could be an individual if it's a solo practitioner, or it could be a large organization. It starts to flow according to policies that that organization set up for how they handle incoming clinical data. There are documentation requirements; there are security and confidentiality requirements.

So, a lot of things happen when patient-generated data moves inside that boundary of an organization. And within the organization, the steps that are shown in the diagram are that there are usually humans involved in receiving, reviewing, making decisions about that information and they usually have choices about how they're going to store the data. It could be data that goes directly into an electronic health record, it could be data that goes into some kind of a data store, but it's not the EHR. It could be tossed into the wastebasket, another data store that gets cleared out from time to time. So there are judgments and there's no guarantee about what happens inside that organization as it starts to handle these different types of data, and we wanted to represent that in the diagram.

So next I just wanted to run through a couple of quick scenarios to kind of bring this out, as to what we're talking about. So the first is the example of Jane with hypertension, actually pre-hypertension, takes her blood pressure at home, records the blood pressure twice a day in a paper log book and once a week gets online and emails her doctor and says, "Here are my readings," and presumably, once a week or so the doctor looks at the readings. The next scenario in diabetes is with Jack and his glucometer and he is taking measurements before meals. His glucometer has a wire that can be used to upload the data to a laptop. He is able to organize and look at his information there; he's also able to move it onto the Web, where he has a patient-controlled health record, and again, it's still under his control, authority to move data and analyze it there. But finally, when he goes in occasionally for a doctor's visit, he will print out a summary of his information and carry it with him into the visit.

The third example with asthma is about Louise, who uses an inhaler when she is symptomatic. This is a hi-tech inhaler, it not only delivers medication, but it has a chip on it with a GPS technology, and it delivers information wirelessly to the cloud, so it's possible to aggregate information -- oh, thank you for advancing; I'm not doing that. It has the ability to aggregate not only the medication that she's using, when she's taking it, but where she is, can correlate that to environmental conditions and so on. And that data is patient-generated and is accessible to providers or perhaps researchers or others who are authorized to look at it. And the fourth scenario is one of a medication list update. In this case, Sue is at the pharmacy and gets a printout from the pharmacist that includes a bunch of information, medications that are listed -- allergies, recent vaccinations and basically a summary of what's in the pharmacy system. She notices that this is different than what's in her electronic health record because from a patient portal that she uses, she can see that the medications there are different. And so she takes a snapshot, a photograph, of the piece of paper she got from the pharmacy, attaches it as a secure message, sends it in to her doctor's office and her hope/expectation is that that will be useful for reconciling the information in the record.

So the point of these examples is to show the variety of ways, of scenarios that relate to patient-generated health data; this isn't all of them, we are sure, but we had to focus for the purposes of the white paper. And I just wanted to add a little bit more context that in working through this, we appreciate that there are a whole bunch of advances that are taking place right now, that are making this area much more sort of palpable and important. Medical science is moving forward so there's more of a thirst and need for data, electronic health records are getting deployed places where clinical data is managed routinely and then raises the question of, how will this kind of patient-generated data fit or not fit as it approaches and is, in some cases, stored in EHRs. Sensors are proliferating and generating lots of data -- mobile technology, as Paul mentioned, is bringing this into the grasp of consumers. So there's just a lot of reasons to anticipate substantial growth and acceleration in this area. We also know that the capture and the flow of the data may be fully automated; but, it may be completely non-automated, carried in somebody's head or on someone's piece of paper and shared verbally. We know that the capture and the flow processes are highly variable, as illustrated in the scenarios, and we also know that the uptake by patients is variable. There are many patients who are not participating, will probably not participate even if given the choice, and there are many providers and organizations and others who at this point, have variable levels of interest and of participation.

So, now I want to talk about the issues that were identified and laid out in the white paper. Starting with technical issues, and there were three areas that we focused on in our conversations with experts; standards, a common or minimal data set and authentication. And in these areas, I would say the focus on technical challenges for the purposes of the white paper, was not very deep. What we found in our conversations was that people felt that standards are very, very important; where standards exist for storing diabetes related data, or demographic data, they should be used, because that will help this data flow as it moves from patient controlled systems into EHRs and to other systems. Where the standards don't exist, we really need to be careful about applying emerging standards or possibly developing standards, but the thought is, that patient-generated data is going to fit into kind of the broad set of clinical data that's being collected and used in other situations. In some cases, it may be new, but many cases it's going to overlap substantially and so standards are important, but at this point, they're neither driving or necessarily dragging the evolution of patient-generated data.

As far as a common or minimal data set, we found that the topic of patient-generated data is very, very broad. It can be clinical data, it can be demographic data, it can be data that's used in research -- there's no way to pin it down at this point, and what's probably the most important is that when a specific use case is identified, that a data be defined for that and it needs to match up as well as possible with other related data sets that are important for clinical care or for operations or other uses. Authentication is critically important and we found that existing methods of authentication that are in use are probably sufficient, it just needs to be practiced and done well and safely. In terms of operational issues, I'm lumping those into two areas, those that are workflow-related and those that sort of fit more with business issues. There's a difference between data that arrives to a clinician's office that was requested and is therefore expected and presumably they have a way of handling that, versus unsolicited; the patient pushes it out and now somebody has to become aware of it in the doctor's office, they need to receive it, process it and so on. And there were concerns about the differences between how those two kinds of flows would be managed.

Doctor's offices are concerned about incoming data coming from multiple sources -- if it's arriving by email, by secure message, by specific interfaces, by voicemail and so on. Those are a lot of data streams to manage; it might actually be the same data, but a different patient, and knowing about them and being able to coordinate those pieces of data is critically important. Contextual information matters. When a clinician requests data, they usually have a question in mind or a decision or some kind of reason for looking at it. When data just arrives from a patient, the context also needs to be clear, especially if it's going be reviewed and used as part of their care. Many organizations that do encourage and accept different kinds of data from patients put restrictions on the kind of information that they're looking for and the kind that they'll accept. For example, if a patient clicks on a pre-visit form to tell the doctor's office about their current medications and their diabetes related numbers and so on, in some cases there isn't a good place for them to just free text in what their questions or issues are, because doctor's offices can be fearful that the processing and the notification about what's in that text box, might not happen right away, and if the patient puts something very significant in there, it could be cause for liability. So what are the content sort of restrictions or guidance that are placed on the ways that patients can share data.

And then in our discussions with experts, it was very, very difficult on balance to figure out if this kind of approach was going to save money or cost more money. It seems that there are good examples where patient-generated data can save time, but also where it can increase the amount of time that might be spent. In terms of other operational issues, the kind of things that we encountered were the fact that global payments for treatment will tend to foster this kind of flow of data, that at high volume automation tools are probably important, that different patient subgroups are important to identify because not all patient-generated data has equal value. So we need to figure out which subgroups and which uses are the most important and try to stimulate those as quickly as possible; that willingness to share data and to receive data requires patient behavior and provider behavior and a lot of marketing about why this is important, and that organizational policies matter a great deal, especially as you look at how data moves into that organizational context.

We talked some about legal issues and Chad Brouillard is here to provide some testimony, so I won't spend a lot of time on this, but, the general consensus from our discussions was that health data that comes from patients and health data that lives in the electronic health record that comes from other sources, has all of the same kind of challenges around it. It can be managed well, it can be mismanaged, it can be missed, it can be… there can be too much of it and that all of those ideas need to be extended as we think about patient-generated data. And there were other issues that came up over and over in our discussions that had to do with limited health literacy as a barrier for patients in understanding why this is important and how to contribute; that time limitations affect everybody, not only providers who are busy, but patients too, and their caregivers; that processing power is limited whether its humans or machines and has to be used wisely. I've already mentioned the point of selecting the most valuable data and fostering that flow, and the point about communication and coordination being very, very important.

The last thing I'd like to focus on then are the recommendations; they were really options to consider -- recommendations is too strong -- but we thought about four different ideas for the ONC to think about. One is to think about how to incorporate some of these ideas into Stage 3 Meaningful Use, recognizing that if EHRs and provider organizations have incentives to create mechanisms for receiving data from patients, that that will improve the possibility, the potential, for sharing data. So what does that mean? It may mean that there are ways that EHRs can be set up to receive information and defining what those characteristics are and making sure that they're in place. It can mean that policies are required, organizations can't say, "we don't know," they have to say, "yes, we understand that people may want to contribute data and we are fashioning our policies to be ready to accept those." We also felt that given the low penetration right now of patient-generated data, it might be difficult to come up with specific areas that certified EHRs are required to address. But thinking broadly, it may be that the concept of a pre-visit communication from patients, which is broadly relevant to most healthcare organizations and encounters, would be a possible place to start.

As far as option two, about the recommendation or the idea is to convene stakeholders and to use those groups for various purposes. I think this meeting is an example of that and I think that stakeholder groups can help to identify high value areas where patient-generated data would be most useful. In the third option, it was to consider how standards play into facilitating the flow of patient-generated health data; and there it may be that the transition of care summary that's already highlighted as part of Stage 2, and will continue, is an important place to look at data elements and commonalities between kind of those areas and what patients might contribute. And option four is to consider additional research, especially research that would help to showcase examples where patient-generated health data is in use and is being used well. Possibly thinking about the ONC eHealth Pledge initiative and where this might fit in, or thinking about how to assess better the current state of providers who are receiving and using patient-generated data and the organizations that have policies that support this.

In closing, I just want to say that this area of patient-generated health data is not new. It's been around for a long time, we're just seeing an acceleration as technology and systems start to work together around it. It is not a simple area, its complex, and so we all collectively need to learn from the experience that's out there, from individuals and organizations, and that it's really important because patient-generated health data can change our mindset in important ways. It helps us remember about the expertise that we all bring as patients as individuals into care situations; expertise about our data, expertise about the decisions and the ways that that data is used. It also highlights patients and people as users of health IT directly, and problem solvers and routine participants in the way that information is shared and used to address health concerns. Patients who contribute their data and access their data get invested in it, and that's really important and something for us to foster. Thank you very much.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you Jonathan. Comments, questions from the committee, workgroup? Oh, John.

John Derr – Golden Living, LLC

John Derr. Just wanted to know why you didn't handle the personal health record connectivity in your report, maybe it was beyond the scope of it or, where does a PHR fit in this whole thing?

Jonathan Wald, MD, MPH – Director of Patient-Centered Technologies, Center for the Advancement of Health IT, RTI

Sure. So the PHR fits in very strongly. It's addressed in the diagram on the left hand side, which I didn't go into detail in, as one of the capture points for data. It's addressed in the example that I gave about the Glucometer data that found its way into the patient controlled record. It's critically important and I would say that the area we didn't address in depth in this report had to do with self-management of patient data. That's a huge and important area; it was just somewhat outside of the scope of what we chose to focus on.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

I have one question. You mentioned in authentication you thought that the current ways of doing it were okay -- does that apply to authentication of patients entering information or messaging to their providers?

Jonathan Wald, MD, MPH – Director of Patient-Centered Technologies, Center for the Advancement of Health IT, RTI

So yeah we were focusing on the way that … in order for data to move into a provider organization that's identified well and reliably, that the patients who are submitting the data need to be authenticated. And so, my comments related to the way that patients today are typically authenticated to patient portals and to other sort of capture devices that require an authentication process. It's very important, I think, that as you're highlighting, that as different kinds of devices are used or different devices get used in the flow of data, that the authentication steps need to be present, no matter what and those are obviously going to vary considerably. The data that I contribute from my sensing devices, the biometric data, may or may not be explicitly authenticated today, because maybe the device makers weren't concerned about other users of the data. So I think authentication is essential, but we didn't focus too much on the kind of many different ways that that would need to play out.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay. In order to honor the high bar the Dr. Lansky and his associates set last time, we're going to have to make sure that we stay on schedule. So, we're a little bit over; we'll take the three, but please limit your comments, please. Okay, Gayle.

Gayle Harrell – Florida House of Representatives

Well, I'll wait because mine really deals with liability issues and I think we're going to have some additional comments on that. I'll wait for mine.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Correct. (laughter) We'll find other ways to say it, I'm sure, we are going to … so, basically what Jonathan has done is teed up a number of the questions that we're going to be exploring through the rest of the day, so we'll hit up the experts. Thank you very much, Jonathan, that's very helpful.

Jonathan Wald, MD, MPH – Director of Patient-Centered Technologies, Center for the Advancement of Health IT, RTI

Great. Thank you.

(applause)

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

And the next panel, dealing with uses of patient-reported information and managing health is going to be moderated by Eva Powell, and we have a number of experts to provide their perspective on this. Eva.

Eva Powell – National Partnership for Women & Familiesfor Women & Families

In the interest of time, while the panelists are coming to the table, I'll just set the stage very briefly. Bios are in your packets, so I'm not going to spend time on those. But I think from the perspective of the group, and particularly my perspective as a consumer advocate, I think it's important for us to understand a number of things, which I think all of us would agree that patient contributed data is really important and it sounds great, but once you scratch the surface, it becomes very, very complex. And I think part of the reason for that is, it's going to be critical for us to understand how do patients make health decisions and the various decisions that are made and that then will flow into what patient-reported data is most useful, as patients make their own decisions, what data do they feel their providers need in order to help them with those decisions. And then on the flip side, what patient-reported data is most useful to care teams and working collaboratively with patients and the various uses of that and then, obviously, how to integrate that most effectively. And then particularly, and it was mentioned in Jon's presentation, which I thought was interesting is, what are the cultural and relational implications for this, because I think they're huge and this is one area where maybe policy has some potential to help with the cultural issues here. So with that, I'll turn it over to the panel and will go first with Nikolai, and then we'll just move down the panel. So, I'll turn it over to you Nikolai.

Nikolai Kirienko – Patient Advocate

Thank you very much. Thank you for the opportunity to testify before this committee. At the White House summit on healthcare reform, it was stated that 5% of patients contribute 55% of the total cost of care. In solidarity with this group, as both a young adult with a chronic care condition, and as a disabled student at UC Berkeley, I hope my testimony will speak to the urgent need to give these patients representation in their medical record that they do not have today. We, the people providers call patients, most often navigate care by voice. We tell our stories in clinic and at the bedside and in search of a cure for what ails us; yet we are not always heard, especially when our illness cannot be easily seen by others or ourselves.

From ages 12 to 18, I hardly looked sick, despite years of disabling symptoms and semesters of missed school. I was airlifted from a ski resort with a full bowel obstruction, but on the day my intestines had finally scarred shut from the progressive inflammation of Crohn's disease, not even my family would have guessed. Through six months that followed at Children's Hospital Oakland, I was unable to eat and received nutrition through a surgically placed central line. A teenage friend in the hospital, Anastasia, also battling colitis had one as well. We both developed a severe complication at the same time -- a blood clot at the end of our central line. My arm swelled up like a water balloon, my hand looked like a purple Mickey Mouse glove. I was the lucky one. Anastasia's clot went undiagnosed until the day she underwent general anesthesia for emergency surgery. Her clot broke off, traveled to her lungs and she coded on the operating table with a pulmonary embolism. They were unable to save her.

This experience made a profound impact on my life. Later, in college, as I was being wheeled into an operating room in Boston for my second surgery, I noticed a trace amount of swelling in my fingers. All scrubbed into their operation, my team of surgeons did their best to convince me that it was nothing. I knew that this was not how my story was supposed to go, I disagreed with their assessment. I revoked my consent on the operating table and I asked for an ultrasound to locate what I believed to be another undiagnosed blood clot at the end of my central IV, called a PICC line. Reluctantly they agreed. The ultrasound revealed a clot.

Fast forward seven years, multiple surgeries and five identical blood clots later, I found myself on an operating table in need of central access once again. This time my care team knew the story well and everyone was in agreement, we would not be repeating that same procedure, yet down in the OR they began to numb the fold of my arm, prepping me for a dreaded PICC line. I froze, this was not the verbally agreed upon plan. In a panic I recited my story. The folks in the masks were unconvinced by my invisible history. Within 24 hours, I had a deep vein thrombosis in my right subclavian artery. It moved to my lungs and I had a pulmonary embolism. Why am I sharing this story with you today and what does it have to do with standards for patient-generated data?

Patients are a vital source of tacit knowledge not always included in the medical record, yet we have but minutes at the point of care to verbally transfer up to a decade of experience and preferences for care. Democracy is defined by participation, so how can it be that our healthcare records are not. Patients make life and death decisions with the aid of this document. We should have a right to see it when it matters most, when decisions are being made, not thirty days after. Our constitutions, physically and as a nation, should align in the electronic health record where life, liberty and pursuit of happiness rely equally upon them both. As an incoming student at UC Berkeley, they tell us you have all the resources to change the world; I believe them, and with a grant from the Robert Wood Johnson Foundation, I set out to give patients a voice in their care that I never had. We developed an app that enables patients to record observations of daily living, allowing them to visualize their experience on an iPad which they can share with the providers at the point of care. They can track pain via SMS, weight from wi-fi weight scale and sleep and activity via a Fitbit activity monitor in addition to medication adherence and lab results entered on an iPhone among other measures, equipping a more complete view of a patient's health. The simple idea was to create a common frame for collaboration, to empower a patient and provider to see and discuss the same health story at the same time, when it matters most, face-to-face at the point of care.

However, in our findings from Project Health Design, we discovered technical barriers to collaboration in the workflow. Patients were hand transcribing lab data from their patient portal into our app as a means to see their data altogether in context. Physicians were able to see trending daily weigh values on their patients for the first time instead of at the usual three month intervals they're used to; yet they still had to eyeball the graph and write a text note for the chart, losing the value of the data itself. What I'm here to say to you today is please make meaningful use a dynamic two-way street, a national open API for health record data. Grant patients easily consumable access to their data on mobile devices and make interaction with health data as simple for a patient as logging in to Facebook or Twitter or their bank. Besides unleashing an ecosystem of innovation for app developers that can engage patients and caregivers in their health on a scale equal to the great challenges we face. By removing these barriers to collaboration, it will unlock to potential of mobile devices to function like the digital equivalent of the patient whiteboard hanging in virtually hospital room across the country. Above all, please enable patients, providers and their caregivers to see the same story at the same time. It will empower them to write that happy ending that our system deprives thousands of Americans who, unlike me, are losing their lives to easily preventable medical errors every day of year, as we speak. Thank you.

Eva Powell – National Partnership for Women & Families

Thank you. Kate.

Kate Goodrich - Centers for Medicare & Medicaid Services

Well that was very powerful, compelling testimony and so now, in complete contrast, I'm going to give the boring government testimony. So, I'm Kate Goodrich, I'm a senior advisor in the Office of Clinical Standards and Quality at CMS and I'm here on behalf of Dr. Patrick Conway. So, CMS is committed to improving care for Medicare and Medicaid beneficiaries through its Quality Measurement and Quality Improvement Program. To this end, CMS is shifting from a purely fee-for-service payment model that rewards volume to one that rewards providers that deliver better patient outcomes at lower costs. The Affordable Care Act has significantly expanded CMS' quality reporting programs to additional settings such as skilled nursing facilities, hospice facilities, long term acute care hospitals, and has authorized the implementation of value-based purchasing programs as one lever to improve care. The Affordable Care Act also required the development of a National Quality Strategy, which was first published in March of 2011. Version 2 was published this year in April.

The National Quality Strategy really provides the nation, and I emphasize the nation, not just the Federal Government, with a framework for quality improvement and sets priorities for quality improvement. CMS is strongly committed to the implementation of the National Quality Strategy, which identifies three high level aims for the nation; better care, better health for populations and lower costs, as well as six priorities. One of these priorities is ensuring that each person and family member is engaged as partners in their care. CMS has long invested in the development and the use of patient-reported metrics, which can measure not only patient engagement and experience, but also importantly, patient-reported outcomes. One example of patient experience measures is in the CAHPS program, the Consumer Assessment of Healthcare Providers and Systems. These surveys were created in conjunction with the Agency for Healthcare Research and Quality, and I'm going to start by focusing on the CAHPS for Hospitals or HCAHPS.

Three broad goals have shaped HCAHPS. First, the survey is designed to produce data about patient's perspective of care that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. Second, public reporting of the survey results creates new incentive for hospitals to improve the quality of care. Third, public reporting serves to enhance accountability in healthcare by increasing transparency of the quality of hospital care provided in return for the public investment. With these goals in mind, CMS and HCAHPS project team have taken substantial steps to assure that the survey is credible, useful and practical. The HCAHPS is composed of 18 substantive items that encompass critical aspects of the hospital experience from a patient's perspective. These include patient communication with doctors, communication with nurses, responsiveness of hospital staff, cleanliness and quietness of the hospital environment, pain management, communication about medications, discharge information, the patient's overall rating of the hospital and whether or not they would recommend the hospital to others. On average, it takes about seven minutes to complete the HCAHPS survey.

In May of 2005, the HCAHPS survey was endorsed by the National Quality Forum and beginning in July of 2007, these measures were used in CMS' inpatient quality reporting program. The Affordable Care Act includes HCAHPS among the measures to be used to calculate value-based incentive payments in the Hospital Value-Based Purchasing Program, beginning with discharges in October of 2012. CMS has also supported the development and implementation of other CAHPS surveys such as the Clinical Group CAHPS, which is used in the Medicare Shared Savings Program or the ACO Program, In-Center Hemodialysis CAHPS and Home Health CAHPS. The CAHPS surveys are, of course, also used in the Medicare Advantage Program. The CAHPS surveys are really only but one example of patient-reported outcomes or experiences, the primary one that we have at this point in time.

So to further address the priority of patient and family engagement, and to foster the use of patient-reported outcomes, CMS is developing Clinical Quality Measures that incorporate patient-reported information. For example, in the Meaningful Use Stage 2 Proposed Rule, there are a number of measures of patient-reported outcomes; these include measures of changes in functional status, remission of depression over time and quality of life, for people with depression. CMS plans to further incorporate patient-reported outcome measures in our ambulatory care, post-acute care, hospice and other reporting and payment programs over time. We expect that over time patient-reported outcomes measures will grow in these Medicare Programs, as well as in the CHIP and Adult Medicaid Programs, and will be critical for quality improvement programs and demonstrations for patients with dual-eligibility for Medicare and Medicaid. Examples again include measures of functional status or change in functional status over time, measures of symptom improvement or change in symptoms, such as pain control, and quality of life measures. CMS is actively working with its Federal and Non-Federal partners to align these and other measures across programs within CMS as well as across all of HHS and with the private sector.

CMS investment in these measures has been to convene national experts in the field of patient-reported outcomes to understand best practices and medical evidence. We have then invested in the creation of specific measures, if measures did not previously exist in key topic areas. The development of these measures includes feasibility testing, reliability and validity testing, as well as sponsorship for endorsement with the national endorsing bodies like the National Quality Forum. We're learning a number of lessons from the development of these measures. Our feasibility testing has shown that measures of functional status change are currently easier to do within a continuity of care practice, such as a primary care practice. Measures of care that cross organizational boundaries, such as an outpatient practice, a hospital or post-acute care setting, require interoperability between systems. Our field analysis has shown that these interoperability requirements face larger feasibility hurdles. We have also identified issues of how best to use data standards to attribute the responses to the appropriate person. Most EHRs and/or audit logs store system user information to attribute a response, such as to a nurse who is logged in. Attributing a response to a patient or family member who may not have signed into the system, needs further development from a data standards and EHR system perspective.

Eva Powell – National Partnership for Women & Familiesfor Women & Families

Kate, I'm sorry to interrupt, but time is up; so if you can wrap up.

Kate Goodrich - Centers for Medicare & Medicaid Services

Okay, sure. So, just to wrap up. CMS will continue to work towards ensuring that each person and family is engaged and is a partner in their care. Use of patient-reported measures is a very strong priority within CMS and across HHS, and we'll continue to support the development of patient-reported measures and to expand their use in our programs across the agency. Thank you. I'm sorry for going over.

Eva Powell – National Partnership for Women & Familiesfor Women & Families

That's okay. Kathy.

Kathleen Frisbee - Veterans Health Administration - Director of Web and Mobile Solutions

Hello. I'm Kathleen Frisbee and I'm pleased to be here today representing the Veterans Health Administration. The VA aims to improve the health of veterans by providing technologies that actively engage them in their health and their healthcare. To support its vision of the future patient-centered healthcare delivery model, VA is using technology to expand care beyond the traditional office visit. This model identifies patient-generated data as playing an important role in enhancing the veteran experience and improving the health of veterans and in gating efficiencies across the institution. Patient-generated data will offer opportunities for VA healthcare teams to partner with veterans and family caregivers in the management of their health and the behavior that affects their health. In order to effectively leverage patient-generated data, challenges have been identified that we are currently working through in the VA.

VA has been successful in developing a number of tools that face patients including the VA's personal health record called My HealtheVet, Home Telehealth, point of service kiosks for appointment check-in. Development is underway on a number of technologies that gather data from patients in robust and systematic ways. These include, but are not limited to, health risk assessments online, patient-reported use of prescribed and over the counter medications at the point of care, mobile applications for pain management, PTSD symptom reporting, journaling and personalized patient care plans. These initiatives underscore the Departments commitment to transform the way care is delivered and improve healthcare coordination between veterans and their healthcare team. They also point to a commitment to increase veterans and families direct participation in their care. By partnering with patients to collect and share data, and by offering alternative methods to do so, veteran's health can be positively impacted. Increasing amounts of data flowing between patients and their healthcare teams between visits has the potential to improve the support of patients when and where they need it, and to increase the personalization of care as well as the quality of care and communication.

As companies move into the consumer health market, there will be a rapid increase in the devices that can collect data about patients and that can be shared with the patient's healthcare team. This data will be an important commodity in the healthcare marketplace and a key component of a healthcare organization's success will be how effectively it uses this data to improve the quality of the healthcare they deliver. The VA has identified a number of challenges in working through these issues. As increasing amounts of data is generated by patients, the VA has had to develop a strategy to fully leverage the potential that this data provides to improve the partnership between patients and their healthcare teams.

The following issues are currently being addressed by the VA: One, veteran experience and value. Designing applications that have value and utility to the veterans and also designing applications to collect patient-generated data across multiple platforms for a seamless experience for veterans. Two, improving veteran health data, designing applications to support enhanced clinical support and patient healthcare team data sharing. Standardization. Standardizing the ways in which patient-generated data is collected, stored, modeled and displayed and standardizing the decision support algorithms that process the patient-generated data. Number four, sharing and workflow. Developing mechanisms to filter and review data types for integration into the clinical systems. Developing policies determining what patient-generated data is shared and how it is accessed by the health care team. Five, synchronization. Synchronizing patient-generated data collected across multiple platforms and modes of access and integrating patient-generated data with healthcare team data to support shared decision making. And finally six, security. Ensuring the secure transmission and storage of personal health data.

In conclusion, VA believes the patient-generated data to be a key component of using technology to improve the health status and healthcare of veterans, and is working to address challenges in order to leverage patient-generated data. We are committed to working together with Federal partners on this issue. Thank you.

Eva Powell – National Partnership for Women & Families

Thanks Kathy. David.

David Lansky – Pacific Business Group on Health – President and CEO

Thanks for letting me present a perspective from purchasers. This will compliment, I think, Kate's comments from the point of view of CMS. So I wanted to talk to you today about how payers and purchasers are looking at the availability of patient-reported data. And in general, I've contextualized this by saying the purchasers are interested in the AAA, and broadly speaking and we're trying to see how the addition of patient-generated data can complement our ability to improve health in society and do so in an affordable way. The three things I want to talk about briefly are the purchasers context for looking at this question today, the uses purchasers are making of this kind of data and some of the implications for the policy making process.

In general the purchasers are not convinced that the current care model is the optimal model to use resources to improve health, and for that reason, they are looking for ways of evaluating the healthcare system and helping both purchasers and patients make better decisions about where they seek care and what kinds of care they seek. We observe very high variation and very high and variable resource use without corresponding impact on health; so the ability to measure health as an important outcome of the care system and then to address resources that maximize health is really what we're after. And of course one of the best ways to measure health is by exploring the patient's own reports of their health status, quality of life, symptoms and so on.

So the purchasers have been very interested in setting external metrics which are available to evaluate the performance of the healthcare system, and having patient-generated data as part of those metrics is considered really indispensable, much as Kate described earlier. What we're trying to do is assess whether providers and approaches to care are providing value to society; and without patient supplied data, we are not able to do that frankly. The purpose of this is both to target provider's attention on opportunities to improve health and to help patients and purchasers make better decisions.

There are really three ways purchasers are now using patient-generated data and they're quite different. One is directly, that is, patients are…sorry, employers are designing their own healthcare programs based on patient supplied data, such as health risk assessment information. Secondly, they are wanting to use this data to evaluate care and thirdly, they want to explore new applications, really disruptive applications, which can redesign the care model around the patient's own reports of information and self-care tools. So on the first of these, health risk assessment and biometrics; employers have a very strong interest in these tools. One of the challenges, however, they have is that the employers are often deploying programs to capture health risk assessment data and then help employees get into appropriate programs to manage cardiovascular risk or smoking or obesity or other factors based on the self-reported health risks. However, the data that is captured through that infrastructure of wellness programming and health promotion programming rarely makes it to the provider's infrastructure. The EHRs aren't able to capture that data, health plans aren't able to use that data; so we have a disconnect between the employer's good intentions around supporting health improvement and the health delivery system's ability to capture that data.

Secondly, we are very interested in the evaluative data from CAHPS and other patient experience ratings and increasingly, patient-reported outcomes. In California, our organization has invested in a joint replacement registry in orthopedics, with a very strong emphasis on pre and postoperative patient-reported functioning and symptom information. So part of what we're trying to do in that program is determine which providers in California are doing a better job at restoring patients to high functioning. That's obviously a very high value to the employer to understand that, and we're disappointed that the healthcare system hasn't taken that on as a system-wide responsibility, so now the employers are directly investing in that kind of work. And then thirdly, purchasers are very supportive of increasing patient engagement in a variety of ways; secure messaging, shared decision making, home monitoring, self-care, and even some of our members are investing in product development. General Electric and Intel have formed a joint venture called Care Innovations, which is specifically oriented toward enhancing the ability to support patients in their own self-management and self-care from home. So these companies are very much committed to expanding capabilities in this regard.

Our members are somewhat interested in the Health 2.0 applications, but frankly, it's been low so far. I think partly because of the lack of demonstrated impact on health from these applications. They're also interested in the Social Media applications. A number of our members are building platforms on Facebook and elsewhere to support peer-to-peer support among patients, among employees around their common health issues. So, let me just conclude with a couple of implications I think of what these points of purchaser interest in the work that we're all doing. First of all, there's a strong interest in involving patients in the design of performance measures; so helping NQF and other bodies bring patients to the table to shape what should be measured is a core value of ours.

Secondly, we want to capture patient evaluative data systematically. Now that is intentioned somewhat with the patient-generated data coming into the EHR; so finding an architecture to both evaluate care at arm's length and embrace that evaluative data in the course of care is an important challenge for us. Thirdly, we want to see that standards for patient-generated data allow integration across the different platforms and users. And the last thing I'd say is that we want to see an architecture for quality measurement which assembles data from the home and the patient, as well as from the clinical environment, and I would hope that this Committee will not sub-optimize the use of patient-generated data around the EHR, but instead think broadly about the multiple purposes this data can be used for. Thanks very much.

Eva Powell – National Partnership for Women & Families

Great. Phil.

Philip Marshall – Healthline Networks

Good morning. It's a pleasure to be talking with you this morning. My background is as a physician trained in surgery and then Public Health and Preventive Medicine; but really, for many years as a product strategist who has helped technology companies to help consumers, patients, to gather, store, manage and share their data, to be able to share their voice with healthcare provider organizations in the form of patient satisfaction; and then most recently, in the area of mobile and social environments in which consumers can help to share their point of view and their data back with care providers. I wanted to share some of that experience with you. As Kate spoke, she spoke to some of that experience, which is with the CAHPS surveys, certainly with regard to those surveys and some of the other emerging surveys that are supporting patient centered medical home efforts, account care organizations and patient-reported outcomes. We're already seeing that the patient voice is beginning to get into the point of care, which is very, very encouraging, but methods of patient data collection that are lengthy and formal.

I'd like to talk a little bit about how some of those methods, and if that's the kind of patient data collection that we're talking about first and foremost, how that may actually be at odds with the very mobile and very social nature of how people are beginning to interact with their electronic world. And so I believe it's important, as part of Stage 3 Meaningful Use planning, that we recognize the reality into which we would be placing these standards. I believe that it's in 2016, in which these standards are likely to first take effect, and one's already seen in just the last few years, the kind of transformation that we've had with regard to mobile and social networks. We had 35 million iPhones sold in just the last quarter alone; half of American households now have smartphones in them. We know that Hispanic households and African-American households exceed smartphone use by approximately 20% over white households, and so this presents quite an exciting, but very rapidly changing dynamic; and it's important to recognize that as we consider these standards.

In my opinion, patients will insist upon using their mobile devices with whatever security settings they deem appropriate, to interact with everyone, and that includes, of course, their healthcare providers as well. In my opinion, secure portal only interaction by patients just won't be in line with their other interactions in their world; and it's similar. I think we're already seeing a little bit of an early indication of how some of the requirements that we have might begin to be at odds with some of how they interact with their electronic connections with the use of email. I know that as a person who's part of a practice that emails with their patients, that I get frustrated when I get the indication that I've got a secure message waiting for me, rather than simply being able to email my doctor and being able to agree to simply email my doctor, and so that, perhaps, is an early indication.

The mobile health experience, by the way, cannot be, and it won't be, simply a mobile app that stands alone. Of course it would have to take advantage of all those things which connected mobile applications can take advantage of and that's, of course, they network at all times, begin able to take advantage of social connections, being able to take advantage of being location aware. And so that's really going to be, I think, the reality of how we need to be able to interact with patients as well. Of course EHR systems have a distinct advantage here, they've got a tremendous amount of personal data on patients and so being able to leverage patient-generated data is critical; but not simply to bolster the information that supports the visit, but rather to create more of a supportive and ongoing environment that allows the patient to generate that data between visits, and then be able to share that.

I believe it's critically important, as has already been established, that the patient be able to download their data, and congratulations on getting that part of the process going. That's going to be critical for patients to be able to do so easily, but they also need to be able to share their data back with the care provider at their discretion. And I've described in my written testimony, the notion that this field is going to evolve rapidly, that the patients will need to be able to answer simple questions like, "we saw you in the office last week, how are you doing?" Now that's a groundbreaking idea, isn't it; or asking patients about their expectations of care up front, and then asking if we met them. Those kinds of things being able to be shared back with the care provider setting is going to be critical, and I think there are ways that we'll be able to accommodate that. And that you so much for your time.

Eva Powell – National Partnership for Women & Families

Great. Thanks Phil. And Dan.

Daniel Campion, MBA - Research Director at Quintiles Outcome

Good morning. Thank you for this opportunity to testify on the topic of patient-generated health data and patient registries. My name is Daniel Campion. I'm a Research Director with Quintiles Outcome, working primarily on patient registries, pragmatic clinical trials and other observational studies for medical associations, patient advocacy foundations and government agencies. I appreciate the opportunity to address you at this important time. As we embark on the development of Meaningful Use Stage 3 criteria, the focus is shifting to patient-generated health data and we are already seeing more EHR vendors and providers beginning to use the web portals needed to send outbound information to patients as required under Stage 2, to collect the incoming information from patients.

The infrastructure is being established for healthcare providers to access an increasing amount of PGHD for a variety of purposes. My written statement and comments today focus on how these data can be used to build multi-site patient registries that can be used for quality improvement, benchmarking to evidence based guidelines, the public reporting of quality measures, maintenance of certification and outcomes research. Centralized registries are growing in prominence and should be seen as a routine part of this new electronic ecosystem. Patient-reported outcomes, or PROs, represent one type of patient-generated health data. Existing research has demonstrated that discrepancies exist between patient and clinician estimates of the prevalence and severity of patient's symptoms, as well as functional impairments. This disconnect highlights the need for direct patient reporting. Collectively such reports of health status, taken directly from patients without interpretation by clinicians, are known as PROs. PROs are more reflective of underlying health status than physician reporting, which is important for clinical research. PROs also contribute to health management by facilitating the discussion of important symptoms and quality of life with clinicians.

A patient registry is defined as an organized system that uses observational methods to collect uniform data for a population defined by a particular disorder, disease, condition or exposure, and it serves a predetermined, scientific, clinical or policy purpose. Patient-reported outcomes are a critical source of data for a wide variety of registries including registries for studying the natural history of disease, examining effectiveness, monitoring safety and measuring quality. Registries typically can evaluate treatment effects in a more real world population that clinical trials, improving generalized ability. Registries also can be designed to answer specific questions that affect clinical practice, but were unaddressed in pivotal clinical trials. For example, registries may follow patients for long periods, five to ten years, to obtain critical data on long-term outcomes, or may collect data from a large number of patients to assess the likelihood of a rare side effect.

Importantly, when partnered with electronic health records, registries can capitalize on the massive amounts of data collected as part of routine clinical care, to create data sets that more realistically replicate the array of inputs that clinicians and patients assimilate in almost every clinical encounter.

Electronic PRO instruments that are directly incorporated into the routine clinical care and thus directly into the EHR, are potentially important sources of PRO data for registry studies. Collection and analysis of such data sets, in the form of registries, offers the opportunity to inform clinical care in ways that are meaningful to all stakeholders in the healthcare system.

We'd like to recommend three possible actions for ONC to consider for addressing a patient-generated health issues. First, in terms of developing Stage 3 Meaningful Use criteria, we believe it is imperative to stress the importance of using validated screening tools and instruments for the collection of patient recorded outcomes information. The use of validated scales and tests, when such tools exist for a purpose needed, is supported by the recent report from the PCORI Methodology Committee. The PCORI report notes, outcomes that are most important to patients may be studies through the use of patient-reported outcomes or quality of life measures. The use of validated tools to collect data on these outcomes increases the validity of the data and the comparability of the results across studies. Use of validated instruments and tools also improves the ability of the data to be linked to other data sources, such as other registries, and makes it more feasible for another researcher to replicate the study procedures.

Second, given the growing use of patient-generated health data in quality improvement and research, especially for patient centered outcomes research, ONC should promote industry-wide standards to facilitate data transfer from EHRs to multi-site registries. One of the simplest and most important ways to facilitate these transfers is by using the standards based interoperability method known as retrieve form for data capture. Retrieve form for data capture, or RFD, is an IHE integration profile that's been adopted as a HITSP standard under the name TP 50. Thirdly, in conducting additional PGHD research to inform policy and practice, we suggest methodological studies to examine the use of PRO tools in observational research. In particular, the field needs to identify best practices for achieving high rates of patient follow up for longitudinal studies, especially those in excess of three years, so that resources can be efficiently channeled to involve the most vulnerable and hard to reach individuals in patient centered care and research programs. Thank you very much.

Eva Powell – National Partnership for Women & Families

Great, thanks. And thanks to all of you for a tremendous contribution already. I'm looking forward to the conversation. As a moderator, I will ask the first question, and I'm going to ask it of Nikolai, but I don't want to put you too much on the spot, and I am interested in others input into this as well. But, clearly from your story and I am sure thousands of others out there, patients have wisdom, even clinical wisdom, that providers do not have and that failing to collect that and communicate that can be, and is, lethal. And so, how do you, as a patient, think we, from a policy perspective…or what would you like to see, rather, in terms of being able to move those verbal agreements, as you put it, to information that's actually viewed and used, on par with clinical information from trained clinical providers?

Nikolai Kirienko – Patient Advocate

It's a great question. So I think one of the things I would pursue is for certain procedures, to be included in the equivalent of an allergy list, that are essentially non-negotiable. I should never have to be on the operating table debating my consent for something that I know is a risk to my life. So where does that fit into the medical record going forward, that's I think, a major issue I'd like to see addressed in particular. Because we can talk about patient-reported outcomes and patient preferences for care, but I think those are the things that we should focus on first, because that's where patient knowledge needs to make it into clinical practice.

Eva Powell – National Partnership for Women & Families

All right, so, include that as a category of patient preferences, am I understanding you correctly, in terms of recording the knowledge you have about your own body.

Nikolai Kirienko – Patient Advocate

Absolutely.

Eva Powell – National Partnership for Women & Families

Any other input there? Go ahead.

M

…stronger than that. Because this was not, you know, a patient preference, this was not, "I like bananas."

Eva Powell – National Partnership for Women & Families

Right, this is knowledge.

M

Right. This was something that had already happened, has been documented as having happening, but was buried in that long history of care. And so I'm hearing that certain things that are powerful risk factors need to make it to a place in the chart, that's a standard part of the chart, that people use like they use allergies or they use a problem list.

Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics

Yes…I was going to say, and Nikolai hi, we worked on a subcommittee together. So, I think the concept that came out, and certainly Leslie is familiar, is "cc me." I think that when we talk about that, the power of that concept. I mean, I know that Gayle's going to ask, and I'm worried too, about legal. But I also worry more about you not being able to tell us what you already know and sometimes the patient's intuitive sense is so much stronger than the clinical facts that we have in front of us. Both of you were talking wanting to hear from your patients, we want to...they want to tell us; so I worry, you know, when we say "in the chart," how are you going to get to that chart, how are you going to know it was documented correctly. I mean, that's our challenge, I think.

W

To me this has implications for…this is a patient-reported outcome; you know certain outcomes are likely to happen for you based on your past experience. It also has implications for patient goals, shared decision making and care planning. And I think the question before us, which is a really difficult one, is where do we put in the chart, how do we document it and share it in such a way that it's likely to be seen and acted upon.

Russell Leftwich, MD – Tennessee Office of eHealth Initiatives

I think it really would be on the problem list. A risk factor, whoever reported it, should be there and would be part of decision support when…so I don't think we need to create a new place, I just think it didn't get there when it should have, maybe, in a lot of cases.

Kate Goodrich - Centers for Medicare & Medicaid Services

Could I also say one other thing, in answer to your question? I think all of these answers are correct but I think we also have to acknowledge, and this is me speaking as a practicing physician and not as a Federal employee. I think we have to acknowledge that in order for this to be patient preferences, patient-reported outcomes, patient-reported information, to be incorporated and used in the electronic health record or other health record, there's got to be a culture change in medicine. I just want to acknowledge that. So, I think what you experienced in the operating room was, in part, in great part, a reflection of the medical culture, as much as it was the lack of information at the point of care that came from you.

And I just wanted to put that out there, because I think for all of our good intentions, that that's still a major issue and maybe one of the levers to change that, over time, is going to be the implementation of policies that require the use of this kind of information, so that over time you have a generation of physicians and other practitioners that this is just part of daily life, is using this information.

Nikolai Kirienko – Patient Advocate

If I could just follow up with that. What I observed over and over in my care was the power of the patient whiteboard for coordinating teams and you saw, for example, procedures that were coming up, simple goals for walking around the unit and at UCSF, they're really driving the patient whiteboard technology if you will, as a lever for culture change. And so I would hopefully like to see that model just transferred into things like the iPad, so that you're looking at the same data at the same time, because the key I think in my story is that when there's a discrepancy, you have to see it at the moment where you can actually do something about it; and I think that means that it would have be in real time.

Eva Powell – National Partnership for Women & Families

Right, thank you.

MacKenzie Robertson – Office of the National Coordinator

So, this is MacKenzie, sorry. I just want to remind everyone to identify themselves for the transcript. So that was Nikolai and before that, Kate Goodrich and before Kate was Russ Leftwich. Thanks.

Eva Powell – National Partnership for Women & Families

And I think I saw…Leslie did you have a comment to that, and then we'll move on to questions.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I did have a comment. It seems…I'm Leslie Kelly Hall, thank you Deven. Also I think one of the consequences, unintended consequences, of standing orders for standing procedures or standing orders for quality measures can be impacted and should be impacted by patient intolerances and patient information; so that there is an opportunity for your information to trump the existing care plans and practices. I think your example of having that information about your intolerances on the whiteboard, communicated to the team, still an order was placed to have a PICC line put in; and it went as far as the operating room. So, I think that is important, as we look at reconciliation of information, it's not just reconciliation of a single data point, but how does that also impact other incoming data or standing data, like orders.

Eva Powell – National Partnership for Women & Families

Thanks. Norma.

Norma Lang, RN – University of Wisconsin

Just a follow up; we have medic-alert bracelets for some of these data, is there a way of trying to identify more things that are important or really a threat to us, to put it into something that maybe has a computer chip or something in it that says for you, no PICC lines; for somebody else, might be no anesthesia of certain kinds; somebody else might be no…pardon me? He has a whole list over here. So, I'm just thinking that this is kind of an antiquated way of…I don't have a bracelet on, but…

Eva Powell – National Partnership for Women & Families

I think we may get to that in some other panels too, as we talk about…I think the point was made earlier that this need not just to be in the EHR, but that we need to think more broadly to other devices. Okay. And I think I saw Larry, yeah.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I can see we're going to have some recurring themes here all day already. So, I guess I want to highlight this, we're moving into a world where there is a big culture change, where it used to be people functioned in islands, and they had what they knew and they interviewed the patient and that's what they acted on. And now, in many, many ways we have teams taking actions, and coordination among team members becomes critical and as we enable information flow between care settings. The process that we've generally labeled reconciliation goes from this, you sort of do it once and you're done, to it really is an ongoing part of working with the information in the chart, what's already here that I now know something new about and I need to act on and rethink what I've already known.

I had an old, I guess I should reference him by name. So, I worked with Larry Weed in the '70s and one of the things he used to say was, we've become our own textbooks; it doesn't matter what the statistics say about an allergy, if you have that allergic reaction, it's gone from a fraction of a percent to a hundred percent. And we need to incorporate that wisdom into how we use things like guidelines and protocols, because we often don't. We just sort of grab it and then we're off and running and the checks that would have prevented the problem have already been bypassed. So, I think there's some really powerful learnings here about what we need to do systematically to better incorporate not just patient data, but all the other provider data that we're now collecting. And the world has shifted.

Eva Powell – National Partnership for Women & Families

Floyd. Sorry, are there comments from the panel or…Floyd.

Floyd Eisenberg – National Quality Forum – Senior Vice President of Health Information Technology

So actually I heard a lot of common themes and this last one, especially the culture change, and how do we incorporate the data. What I heard was, how do we also incorporate the data that the patient has that he or she is sharing through an employer program, or sharing in other means. And, what I want to caution against is that we don't try to solve how that data should be best presented in an EHR, while I like the idea of a problem list and patient reconciliation of it, I think that's where we need some research and innovation of how to best manage this culture change. It may not be anything we could come up with today, and it might be all of them.

But, it's important to say, "this kind of information must be shared and patient data must be there," especially adverse, but also positive experience with care. What really does work, so you don't try something that doesn't work, as opposed to just what works poorly, which you also want to know. And I also think it's important to understand how we can address data that may not really belong in the EHR. The example, and I'm…from the first whitepaper, about data about asthma connecting with weather, perhaps pollen count; that's not something a doctor would think that would belong in the EHR, but it's important in managing that patient. So, I think we need to think about the data that need to be available and how they're used and encourage research to figure out the best way to use it.

Eva Powell – National Partnership for Women & Families

Right, thank you. Charlene.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Actually I have…points. The VA has been well known, over the years, for doing measurement and running your systems based on measurement; so as you look at incorporating patient-generated data into your systems, when you think of the measurement or the process, do you see the measurement reflecting on the measures of a more integrated measure or reducing readmissions or whatever, or do you see separate measures relative to collecting patient-generated data and how that's impacting care. So, just your framework in terms of how you guys are thinking about it.

Kathleen Frisbee – Director of Web and Mobile Solutions, Veterans Health Administration

Well to be honest, I don't think we've started to think about measurement. We're thinking about infrastructure right now. As I said, there are a number of issues that we're trying to work through and it's been repeated here many times, but the standardization and the interoperability of the data is really very, very important to us. But I also think the algorithms that we design to handle the data is important because this is going to be a tsunami of data that's entering our health system, and if we don't have the mechanism, the visual design right in terms of being able to view that data and to be able to see clinical data from the EMRs superimposed with veteran data, it's going to be very, very difficult for clinicians to manage all of this data. So, we're really thinking about that at this point, not about measurement of this.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Okay. And you'll see my theme for making sure what we got on the front end also comes out kind of in the back end in a way that as we capture it, we can measure it. So, to David. You kind of raised the point…the kinds of feedback I get from our customers is, you know, I've got these portals out here and my doctors giving me access and then I'm going to go to my next doctor because I've got a chronic condition and they give me the portal; how am I going to look at this data together. Right, so they kind of ask that question. I'm saying, well that's a big question of the industry. But David, you raised the point relative to, we're challenged a Meaningful Use Workgroup to think beyond the current models of EHRs in terms of how we reconcile and bring together the measurement data. So, can you expand on that, because it's really both ends I think we're trying to harmonize? How do we create that view for a patient, of that whole story, if you will, and at the same time, capture the measures in such a way they're reflective of the experience of the patient in the broader context, in the continuum as opposed to venue based.

David Lansky – Pacific Business Group on Health – President and CEO

Well, I think you said it and yesterday's hearing I think raised the same questions as to whether any node in the network has all the data needed to compute a measure across the continuum or across an outcome over time. And so, that's uncertain at this point, other than big ACOs or large, comprehensive organizations that might be able to claim comprehensive knowledge of a patient's care across settings, and that's a pretty small percentage of patients and for the foreseeable future, will be. It seems like we need an integration platform of some kind, part of it is the standards, so that the data, whether from patient or from clinician, is interoperable, and part of it is a new platform that can integrate and aggregate that data and then produce the kinds of feedback tools or measures that we want. Registry is obviously one of the most current platforms for doing that. So, I don't know the answer, but I think this intermediate layer is one that we as a Committee have to give more thought to, and what rules, standards, etc. can be put in place to support it, and per today, making sure that the availability of standardized data from patients is an equal component of that infrastructure.

Eva Powell – National Partnership for Women & Families

Thanks. I didn't see, Jodi and George, who was first? Okay, go ahead.

Jodi Daniel – Office of the National Coordinator – Director of Policy & Research

So, thank you. This is Jodi Daniel. I've heard a couple of themes already, one that there is value of patient information into the clinical decision making, but that there are challenges in culture and workflow. And so I also heard some ideas about standards, and ways of…it seems to me that if we want to be able to try to figure out how incorporate the patient information into…at the point of care, that we need to figure out ways of helping to simplify that information, either through standards or maybe some workflows or making the systems useable so that it helps in decision making. And I heard some comment about standards, I've heard some positives, we might need some standards in some areas, some concerns about standardizing some information flows when the technology is changing so rapidly, and I just wanted thoughts both on are there areas where standards can help support innovation as well as make it easier for this information to be digested, as well as are there other ways to think about simplifying that information flow either…are there standards of behavior or kinds of functionality, or anything else that we might be thinking about when we're thinking about how to get that information from the patient, that wisdom from the patient into the decision making of the provider. And, I open up to anybody.

Daniel Campion, MBA – Research Director at Quintiles Outcome

I'll take a shot. This is Dan Campion. Just in the context of information that I think it will be important to keep in mind that there are different layers of how information is going to be used and processed. So, if we're talking about immediate enhancing the conversation between the doctor and the patient, that's one level of information exchange. Then, if we're talking about organizational quality improvement and improving problems so that we don't have these systematic safety problems. And then if we're trying to create generalizable knowledge through research, we've got different layers and different uses of this information and I think it would be inappropriate to just kind of lump it all together and to think we need the same fire hose of data for every single purpose. So the care that you're working on with the legal issues…when we deal with a quality improvement project versus a research project, all the barriers have to be thought about, the HIPAA standards, etcetera. So, I just think it's important to kind of keep all these layers in mind; but one of the exciting things that you have are setting the pipes down, and so the idea of the retrieved form for data capture and ways to make sure the data becomes available. But then there's a lot of responsibility by the users, in terms of how they're going to use it. And those standards have to stay in place; the peer review, the internal quality improvement systems, all have to be in place, to make all these data, turn them into information.

Philip Marshall – Healthline Networks

I'll make a quick comment there. This is Philip Marshall. So, in my opinion, I think it's going to almost be impossible to imagine this ecosystem which is going to help support patients to document what it is that they feel is going to support their health; whether in support of the clinical encounter or otherwise. So, I'm personally dubious of establishing instruments that would collect particular pieces of information when in 2016, patients might have the attention span that I generally have, and that is, much shorter than instruments that are validated today. However, interfacing the electronic health record for that download process in a way that's easy, and I would ideally like to see that easier than the CCD, would be fantastic. But on the flip side, allowing a patient to be able to share their information back, not completely dissimilarly to how an email today, coming back into the office, might be able to be stored. But you can almost imagine, akin to a patient's health drop box and sending an invitation to the practice to accept the access to that and while there are definitely policy liability concerns appropriately, there are solutions to these concerns; and caveating that access by the provider to such information, I think, could be handled in such a way to make that work. But I believe that the flexibility, as opposed to over-standardizing instruments is key.

Nikolai Kirienko – Patient Advocate

If I could respond.

Eva Powell – National Partnership for Women & Families

Nikolai, yeah.

Nikolai Kirienko – Patient Advocate

Here I go again. To have standards could impact the workflow. It would be fascinating to consider how we could prevent that situation that happened to me with the PICC line in the future if there were a messaging standard that sent me a text message saying that I have a procedure coming up for, let's say, a PICC line, so that I had some idea of where I was going when they came into my room with that wheelchair. Because that's what you do with a patient, you're in your hospital bed, they come in with a wheelchair, you're going for a procedure. You get in the wheelchair, I didn't know until I was on the table that the conversations I had with my specialist and my hospitalist did not actually make it into the EMR order. So it wasn't until they were actually going after my arm that the horror of the situation became apparent. So, that would be one interesting aspect, if there was some sort of messaging component. And would also just second the comment made earlier, in terms of the workflow and the hospital bracelet; if it could be made simply incompatible for them if they're trying…I know, I've heard EMRs are useful for billing codes, if it was just simply incompatible for them to scan that PICC line pack, scan my bracelet at the same time…so they would try to scan and it just wouldn't work and then that would cause an alert. So…

W

That's great.

Eva Powell – National Partnership for Women & Families

Go ahead Kathy.

Kathleen Frisbee – Director of Web and Mobile Solutions, Veterans Health Administration

This is Kathleen Frisbee. I think that you could help in three ways. One, and everybody's said it over and over, but the standardization of the data. So in the VA what we're doing is when people create mobile apps, you don't get to post it, to have that app certified, until we've determined that it maps to a common information model. So choosing a common information model and saying, everybody has to map to that, that would be huge. Secondly, again, you need to standardize the decision support algorithms. So, we have algorithms for patients and we have algorithms for providers. What we don't want to find ourselves in a situation where developers are creating different algorithms for patients that respond differently with the same data; we don't want that situation.

And finally, the sharing of data is very confusing for us. Some want a model whereby an app, a mobile app is like a prescription, where we say, we are asking you to use this app; and by doing so, we don't want any ambiguity about whether that data is shared or not. That's one model; the data is shared with the clinical staff; that's the way it works. Another model is the patient has the right to make the decision as to whether or not they share that data or not, and that interjects a level of ambiguity in it, that creates confusion. So, we don't have the answer, but we're struggling with this notion of sharing, we're struggling with the notion of, okay there's the personal health record which belongs to the patient, and there's the clinical record that belongs to the clinical team, and what's the relationship and how does sharing work between those.

Eva Powell – National Partnership for Women & Families

George.

George Hripcsak – Columbia University

George Hripcsak. First a side comment; actually there are pilots going on that do exactly what Nikolai just described, like an iPad inpatient, tell them where they're going next and give them a box to say what they think is going wrong with the thing, and that one's built upon the PHR which is then linked to the EHR and that's how that's carried out. My comments actually, that just triggered that thought, but that's the Cupid Project is one example, but I think there are others going on. My comment is that incorporating patient-generated data is a lot of different things and I think we pretty quickly need to get a taxonomy that's simple, understandable and useful. RTI does have a bit of a taxonomy in there, I'm not sure it's exactly the right one yet, and so I just sitting here said, well maybe it's before, during, after and sensor, and so I want your comments on that David and others.

Before means, the data that we would have collected either before, right at the beginning of the interview…of a visit with the patient, like past medical history, and that's really about efficiency and accuracy. During is the most important, that's what Nikolai is talking about, that is, patient participating in the care and after is not temporarily after, it may be during the during, but that's outcomes and it's not stuff that you would have collected, except you want to see how it went. And then sensory is really a different kind of thing. You know, if you put a patient on a Holter monitor, they'd be sensed at home and then the report would come in and you'd incorporate that into your EHR without thinking twice about it; so, we'd have to think about those issues. And maybe there's a fifth one, which is social media, and I'm not sure if that is the right name, but what's different about that, it's not really linked to the healthcare process. The patient may be doing PatientsLikeMe and you don't even know what doctor that goes to, but if the patient wants it, you would want that data informing the EHR also. So, I guess my question is, is there already a good taxonomy of patient-generated data that would be useful for us as we figure out what policy levers to pull, or is before, during, after and sensor data the appropriate one, or whatever.

David Lansky – Pacific Business Group on Health – President and CEO

I don't know the answer. There have been some taxonomies floating around, and this is a new environment. I liked some of the categories you floated, but my reaction is to flip it and say sensor is the dominant category if you like, and there is…in other words, a patient centered longitudinal view, patient has life…functioning quality of life symptoms, and so on, which are…I've seen…there are some oncology patients who have done really remarkable personal diaries where their tracking both objective quantitative data and personal, self-report data; PatientsLikeMe style, which go on for months and months and months, and it's a living record, it's a full health record. And then on that there's a blip of a professional health encounter, but from the patient's point of view that's just a blip, maybe a very, very important blip, but the continuity of their overall experience of managing their cancer is the dominant experience they have, and whether parts of that should be shared with a health professional or an institution or a technology platform or not is a judgment call to the point Kathleen made about when the patient should control the release of that information. So, I'd think about a longitudinal model within which there are points of contact to certain kinds of additional resources that help a person manage their health.

Eva Powell – National Partnership for Women & Families

Other responses? Paul.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

This conversation...I have a little metaphor that came to mind as David and George were speaking, I mean, it's not as if we want a physiologic twitter, and I'm not sure that's going to help. So in a sense, and I think the principle that not all data belong in an EHR, but that all information relevant to patient care decisions do, and our challenge is to figure out, is there an automated, or at least an efficient way, of getting the patient care related information into this "clinical record." It's a bit what Kate Goodrich…the problem's always been there, and they've been handled one person at a time, because they do distribute the information sometimes to the circular repository, but you in effect have to abstract the information out of the data, I guess a little bit like Twitter.

Philip Marshall – Healthline Networks

Yeah, Phil Marshall, quick comment on that sort of inspired in my mind. So, I guess the question then really becomes, is it the systems responsibility to discern that information out of whatever might be submitted, or is this really…are we really talking about a communication tool between people. I was sitting here and I was thinking that I recently went through some patent work with a lawyer, and he simply asked for me to go ahead and share with him everything that I'd put together on the concept, on the idea; and so I did. And he read through it and he said, well here's how I'd approach this particular issue, and I was thinking to myself when's the last time that I had a physician, actually I belong to Greenfield Health, which is a great, very open practice, important; so my experience is probably more like this than most, but I think it's uncommon for the physician to say, well send me what it is that you generated, send me what you have and let's review it together, let's look at it, and let's get some data out of it. And so again, I'll just kind of go back to an earlier comment, I think trying to systematize the discerning of value out of patient-generated data, outside of two human beings using it to help make collaborative decisions might not be the direction I would advise.

W

And that actually is something I've been thinking as we've been discussing, is that we've had…we're still in the process of figuring out how do we approach care planning, but more specifically the concept as a care plan, and it seems to me like this conversation and that conversation are…they aren't the same, but they're very similar and the question is, exactly what Paul said, what is…any information that is pertinent to a healthcare decision somehow needs to be represented, but how do we do that? And I'm just wondering if we start thinking that way, of this notion of patient contributed data and our task in other settings of trying to figure out this notion of care plans and how to represent those electronically, I think there are some commonalities that maybe we should start tracking. So…

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Yeah, going to back to some of the taxonomy and the uses of the patient-generated information, I mean, one of the things that I've heard, that I think may be helpful, at least in my mind to sort out a little bit is, how the data is used as well. So for instance, in some instances we've heard discussion around using the information for more quality improvement across the board as a survey to help the culture change and help improve the system of delivery of care, although its patient-generated. To me, that's a very different and I think we need to think of that differently, than even a survey of, have you met the goals or the expectations, have we met your expectations on an individual basis. So I think as we think about, because obviously there's a wide range here that we're hearing of definition of patient-generated data, because it's all patient gener…there's a lot, but it's being used for very different things and that may be another way to sort of get to where George was in terms of thinking about how to chunk this down into more…smaller pieces to think through as when we think about policy levers and implications, to think about them in that context a little bit more, just a suggestion.

Eva Powell – National Partnership for Women & Families

Thanks. I saw Norma and then we'll go…

Norma Lang, RN – University of Wisconsin

Norma Lang. We've been talking here mostly HIT and the electronic health record. Do we also have the concern about HIE? Is that the next step of what of this data then goes out into the exchange? I've got my hat on from Wisconsin WISHIN, which we are on a data committee saying, what's going to be the minimum data set, what's going to go into an exchange out there. So, is that another step or, because I thought at one point we had that responsibility in this group as well.

W

I guess my thinking is it's both, but…

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

This is Leslie, it's both and I think in the care coordination team we're talking a lot about when healthcare moves from binary dialogue to a collaborative community, these issues become even more…multiplied right, so we have to accommodate both. Your suggestion, I think Amy, also brings up another point to me is that the first thing perhaps that is easiest to do is to respond to a request from a clinician, where a patient is responding back; "This is a survey I'd like you to fill out. Here's a questionnaire I'd like you to fill out. What is your health status? Please provide this observation. Please provide this result that the patient can generate." That seems to be more consistent with the current workflow as a physician will have an observation, a result, a telemetry feed, a biometric feed.

And then going into a patient initiated data, where it's not asked a response, but it's something that now needs to be integrated into the chart, because it's new information. It's that tacit knowledge that Nicolai spoke of, and then perhaps there's that third level which is a collaborative care record, that says that beyond this episode of care, and this binary relationship, we now have a collaborative care model that sits on top of and communicates with, but is something distinctly different and, I'd kind of like to hear the response of the panel to those ideas.

Nikolai Kirienko – Patient Advocate

Well, if I could jump in on that. I like what you discussed before about this notion of patients having journals that document their patient narrative or their progress through care, that can get blips, as you describe them, from let's say the EMR. Since I've been in Washington I've been using a mobile app called Path, and I check into places, take photos and it lets me send that information to multiple social media, APIs, from foursquare, Twitter or Facebook. So one of the things we saw in our project was from the devices, if you have a specific observation that can be redeployed in multiple contexts, that's incredibly valuable. So for example, the Withings Weight scale; that one weight reading from stepping on the scale populates into not only our app, but at least a half dozen other apps and app store, so if we move towards a model where, let's say you had a collaborative care stream, for example. So when I see my primary care or my gastroenterologist, I have a feed that populates in with some of these events. I think moving towards that paradigm of the patient whiteboard, where everyone sees the same data at the same time, the thing that is true for every patient is there at every encounter. So, by default, they are that health information exchange of one and so, to the degree that I can actually have data from other encounters that I take with me, that allows me to even communicate data with providers that aren't on the network, let's say at UCSF.

You know, that's incredibly exciting to me going forward, because what you start to see is actually a patients story unfolding across the totality of their care and so, I feel like as we move forward in meaningful use stages, and we discuss more and more about APIs, that's the kind of world that I think would make a substantial difference in terms of both the patient's awareness and how they're accessing care, as well as their other providers.

Eva Powell – National Partnership for Women & Families

Thanks. We've got like eight minutes left, let's go quickly here and then to Paul and then to Amy.

Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics

This is Liz Johnson. You know Nikolai, as I listened to you talk and Leslie and others, I think this theme of Kate talked about earlier, that we live in a culture where physicians have to make changes, I think everybody has to make a change because we do episodal care, that's what we do. I mean, we can pretend like it's something else, but it's not. And so, when you talk…I loved that term stream of care, not care plan, because I don't think we think that way yet. So somehow, we've got to tear down those barriers and at some point we have to talk about, and maybe we can't get there, but we have fear of the legal ramifications of sharing data, so we self-impose our inability to share not because we don't want to, because we know there are ramifications if we overstep privacy boundaries.

So Nikolai, as you lead and others lead, we need to hear from the patients. I would say to you, you're not representative of every patient, I wish you were. So I think your sophistication and ability to handle data is different; so we need to think simplistically about how we take advantage of the statistics we heard earlier from David and others about how many people have data and make it simple. And then you need to help us understand, what's the most important thing you can tell us about you, so that we can react to that, because we have to start simple and go to big. So, think about those things as we go forward.

Eva Powell – National Partnership for Women & Families

Paul.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Liz, I'll piggyback on that in a sense of, we have a big data problem and I don't know that we've figured out the solution, but maybe information is in the eyes of the beholder. And so, I think the biggest insight was actually Nikolai's suggestion of using a tool that we do have, the CHR, and one of the most effective ways is to put up the allergy flag. We do pay attention to that and that's what…so you've tapped into a tool that works in a certain way, and you've contributed what's important to me. So, just like an email where you can flag something; we all have a perspective and maybe what we're trying to say is, we need to take the…one, we need to take the perspective of the patient, but that we flag information from our various perspectives on the team, which includes the patient, and then use the tool and improve the tool to make those flagged things more and more present when we're making decisions. That's the closest I can come because there is no AI that will do this job for us right now, but I think we can probably, if we flag the things, information is in the eye of the beholder, and make it visible, then we're at least making steps there.

Eva Powell – National Partnership for Women & Families

Amy. We'll wrap up.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, Amy Zimmerman. I was just going to go back to the comment around HIE and something that Charlene had said before. So I think when we think about health information exchange and HIE, at least in a more networked arena, we need to think about patient-generated data going in, but I think we need to really think about the part that Charlene was talking about. Because personally, and we've heard from lots of individuals too, having multiple portals and not…the point of health information exchange whether it's a verb or a noun is really to be able to get that longitudinal view. So I think it's a two-way street. It's what data gets contributed from the patient into that process and that importantly, how does the clinical-driven data and the patient-generated data get combined across organizations, across the spectrum and streamed into one useful tool for both clinicians and the patients, and that's a challenge, but I think we have to think in that way.

Eva Powell – National Partnership for Women & Families

Thanks. Any other questions…okay, thanks Russ. Go ahead.

Russell Leftwich, MD – Tennessee Office of eHealth Initiatives

Nikolai, I understand your vision, but I think one of the potential, unintended consequences of having all that data in all those places is that it's just too much data and it's overwhelming and what we need to be sure we have, that I don't think we have, is the filters to make sure that those mini-systems are seeing the information that they need and not all the data that could be sent.

Nikolai Kirienko – Patient Advocate

I agree, this is Nikolai again. I'll just say that I like that idea of specific encounters though, if you have like an appointment, if there was an alert or something that was generated that described the very top level of your care; it wouldn't necessarily have to be super-detailed. And then one other thing that I'll just quickly say though is that I would also love to see if we're prioritizing use cases, a focus on that 5% of patients that do represent so much of the cost, and those patients are generally hospitalized, and the place that you'll see the most value demonstrated is when they're discharged from the hospital. And so, if I could just put in my two cents for that.

Eva Powell – National Partnership for Women & Families

Thanks. You've gotten at least a dollar cents there. We've got like one minute left, are there any final comments from the panel? All right, great, thank you so much for all of your input (applause).

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks to the panel as well, it was a wonderful panel. And thank you to Eva for managing the time.

Eva Powell – National Partnership for Women & Families

A minute…I don't know if I did it.

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, we gave credit, yeah.

(Panelists changing seats)

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

If we could reassemble and we'll begin our second panel.

MacKenzie Robertson – Office of the National Coordinator

Can the presenters for panel two please take their seats?

Paul Tang, MD – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you everyone, and we're going to begin Panel #2. This one is on Emerging Practices, because there are people already both constructing tools and recording information in this space, and we want to hear from them. So, Leslie Kelly Hall is going to moderate this panel on Emerging Practices.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Great and thank you panelists for coming. Is Suzanne in the room or on the phone? Judy, are you on the phone?

Judy Hibbard – University of Oregon

Hi, excuse me, I'm here.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you for joining us. It's important that we recognize that work is already being done and often recognize that the market does drive new uses. And so this panel will represent a lot of current use and I think future thinking. Before we start with the panelists, there are some relevant announcements that I'd like to make. Last night or yesterday, an HL7 sub-team did approve a scope document to go forward with a consolidated PDA format for patient-generated information, so that's very exciting news. Also, on the standards front, the HL7 Plenary Session in September will be dedicated completely to patient engagement. So, we're seeing a shift in the industry, recognizing the importance of patient engagement and patient-generated health information. So, that's pretty exciting. And I'd like to turn it over to the panel and we'll start with Judy Hibbard on the phone and as Eva pointed out, the biographies are in the packets. Thank you. You have the five minutes Judy.

Judy Hibbard – University of Oregon

Thank you and good morning everyone. I apologize for not being there with you. Ideally, patient-generated data can serve the dual purpose of informing the care process for the individual who is providing the information and can also be used as an outcome measure to assess the efficacy of care. So my remarks focus on the use of the patient activation measure, or the PAM, as an example of such a measure. The PAM measures patient's knowledge, skill and competence for managing their health and their healthcare. Research indicates that patients who are more activated are more likely to get preventive care, to have their biometrics in the normal range and they're less likely to use the emergency department or to be hospitalized. These patients also have lower healthcare costs and this is true even after controlling for health status factors, risk scores and demographics. The evidence also suggests that clinicians can make a difference increasing activation in their patients. Today I want to share with you some innovative practices that are being employed to take advantage of this type of patient-generated data.

In some delivery systems, the PAM is being entered into the electronic health record at the point of care, or collected as part of a pre-visit process. Clinicians then use the PAM as a vital sign to know basically the patient's current capability of self-management, and to tailor their communication and their support to the patient's level of activation. The idea is to encourage the individual, especially low activated, to take small steps that they're likely to succeed at; and we know that these kinds of small successes actually do build competence and motivation. Because those patients who are less activated are likely to be overwhelmed with the task of managing their health. The approach is to use this information in an action plan that is focused and doable, and does not further overwhelm the patient with too many instructions, behavioral changes or information. Further, when the whole clinical team actually has this information, as is the case when it's in the EHR, they can be more effective in providing a consistent approach and consistent messages for the patient.

In addition, clinical teams are using the PAM to be more efficient in how they allocate their own resources. In some patient centered medical homes, the PAM is paired with information on the patient's disease burden or acuity level. They use these two pieces of information to allocate their team member resources and time. So for example, patients who have a high disease burden and limited self-management skills, or a low PAM score, they are allocated more team time, they spend more time with the patient and also they allocate team members who have a higher skill level. So, for example, the high disease burden, low PAM score patient might get more time with the MD and the RN, while patients who have a lower disease burden and a higher PAM score, are referred to community programs, web resources and assistance from a specially trained medical assistant; so clinical teams who are doing this are finding that they can be both more effective and more efficient in achieving their outcomes.

Another innovative use of this information is coming out of delivery systems that are using the patient's PAM score to inform their care protocols. So this could include adopting approaches for reducing system barriers for low activated patients or how they do medication reconciliation or, using the patient's activation level to determine the frequency and method that they use in follow up with patients after a hospitalization. So for example, when referring a woman for a mammogram, if she has a low PAM score, they arrange for her to have the mammogram during her visit, which of course, increases the chances that the mammogram actually gets done. At the same time, higher activated patients are scheduled for their mammogram in the usual way.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

And Judy, can you wrap up please.

Judy Hibbard – University of Oregon

Yes. So finally, the PAM is being used to determine whether individual patients or whole groups of patients are gaining in their ability to self-mange. And this information can be used for accountability as well as practice improvement. I think, as this kind of information becomes more widespread, we're going to see more innovations in interesting ways; but this information is being used to improve the care process. Thank you.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you Judy. Barbara Howard.

Barbara Howard, MD – Child Health & Development Interactive System

Thank you for the opportunity to contribute to the patient-generated data public hearing. I'm Barbara Howard; I'm a pediatrician representing the Center for Promotion of Child Development through primary care and its subsidiary, Total Child Health. We're the disturber of CHADIS, which is a web service for pre-visit, online patient data entry, with in-visit patient specific clinical decision support and post-visit patient clinician collaboration with a focus on Child Health. As physicians we know that patient provided information has always been central to medical condition diagnosis and care, otherwise known as taking a history. We assert that the patients in a modern healthcare system should not only provide data, but also have access to educational resources, decision support tools and collaboratively negotiated goals specific to their identified needs. And these functions can most efficiently come from systems that are based on patient-generated data that trigger the functions. Such collaboration tools can result in improved adherence and health behavior change, which turn out to be key to improving most health outcomes; adherence and health behavior change are essential.

So, we're hoping that the regulations and standards that we'll come up with here are really those that are needed for EHRs to accept patient-generated data in a structured format, and also to communicate with content-specific modules, which we feel are crucial to efficiencies of care, to quality improvement processes and to patient engagement, which is needed for health behavior change, and optimal health outcome, not only for children, for adults as well. So, I think everybody on the Committee has been thinking about the fact that we need regulations so that data is accepted into the EHR from multiple sources, that it's standardized, at least in part, that it's interoperable, that it has a standard vocabulary and that the standards should apply not just to EHRs but to also patient-facing systems. But there are some more subtle requirements that we would suggest.

One is that patient-generated data input operations should be designed to include multiple respondents; this is particularly true for children because they are not responding for themselves. But it also involves making a community of care for the patient, including respondents who are not using any EHR, such as therapists, teachers and early intervention providers. It turns out that most of the care provided by doctors for children at least, and I think for adults as well, involves a team effort and that's not always going to be a team using an EHR. We also need modules to collect and share standardized, and when available, validated psychosocial functioning; not just demographic information, but actual things like mental health screening, as this is the area most likely to support or interfere with health outcomes. The data should also inform and trigger shared decision-making tools between the patient and the provider, not just during the visit, but asynchronous care, apart from the visit. These include things like problem solving counseling and motivational interviewing, which have been shown to improve health behavior change, and it could be used during visits, but it's not being used, where patient-generated data can begin the collection of this information into a counseling interaction used during the visit with electronic follow up after the visit with the patient.

So, we think standards should facilitate interoperable modules that both send and receive data. We think that one of the things to keep in mind is that if the doctors don't ever use the system, it's not going to do any good. So, EHRs are not motivated to include or update content specific areas, whereas modules would do that; healthcare of children is often left out. Modules also could be created by quality improvement leaders who are committed to facilitating the required monitoring and interaction with doctors in the field to create quality improvement data for recertification. Now recertification is required of doctors and it motivates them to use the system to its fullest.

Now I'd like to speak to the specific questions we were asked to address. What are the emerging best practices in integrating patient-generated data into EHRs? Well, we've answered this in our written material, but the key point I'd like to make is that we believe, as you do, that CDAs while allowing for a robust architecture for exchange and use of patient-generated data, also are a barrier unless they're required. So, I'm delighted that you're making the recommendation. There also needs to be a place for data to reside, besides the CDA, or other document used to transmit it, that allows providers to use data aggregated from arbitrary sources for a number of purposes. Less strict standards such as green CDA would also reduce barriers for smaller organizations. Without these steps, the industry will become increasingly fragmented.

What is the role of mobile devices in integrating patient-generated data? Well, we have a system called CHADIS, and we know that mobile technology is really important as patients of low income and low education often still have cell phones and that's their main way of accessing the internet. The CHADIS system is designed and tested to provide a high level of accessibility to families of low income and low literacy, even though it's a computer system. It facilitates collection of patient-generated data in several ways. One is interactive voice technology, which uses a regular touch-tone phone. The patient hears the questions, pushes the buttons for the answers, the results flow seamlessly into the electronic record.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Barbara, I need you to wrap up.

Barbara Howard, MD – Child Health & Development Interactive System.

Better yet, iPhones and iPads have been shown to reduce barriers and can even read the questions aloud. So the way CHADIS works is the office sets up a set of validated questionnaires, simply tells the patient when they call for an appointment to go to CHADIS.com and enter the phone number, the patient's login at their convenience outside of visit time and complete questionnaires. The results flow to the clinician for use and the results, specific results, trigger decision support, including patient specific templates that combine specific answers to questions with guidelines for care that are national standards, and resources for the patient that go to a memory book keepsake that's populated for the family to motivate the family to be interested. They see this memory book, they see alerts about health risks that have been generated by questionnaires, they see notices send by their doctor and they can get coupons that motivate them to use the system.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

And we'll ask further questions as we go on. And Elliott?

Elliott Fisher, MD – Dartmouth Medical School

Great. Thank you very much; it's wonderful to be here. I'm Elliott Fisher at Dartmouth Medical School. We all recognize the problems with the U.S. Healthcare system, lousy quality, fragmented care, impossibly rising costs. There's broad agreement that to fix this, we need to move to payment systems, performance measurement systems and benefit-designs that both support wise choice on the part of patients and support the improvement of care by clinicians. That happens both directly through tools that support frontline clinical improvement and indirectly, through the accountability structures that can be built on good performance measures. Patient-reported measures, whether it's of health outcomes, functional status, patient engagement as Judy mentioned, are critical to all of those aims. And, it's been shown I think in a number of systems, that it's feasible to do so.

I'll speak briefly about Dartmouth Hitchcock's adoption of patient-reported measures in their Spine Center, where I had the privilege of being treated when I had a ruptured disk. Basically the notion is that you…the workflow identifies a patient who is eligible for a particular set of patient-reported tools, in this case, the SF-36 and a picture that allowed me to show where my pain was being experienced. That happens either online prior to the visit or, if you are like me and forget, you show up and there's a tablet that makes it possible for you to fill it out in the office. By the time I'm in the office with my clinician, that data has been integrated with all of the information in the EHR and presented as both my functional status scores on the various domains of the SF-36 and a pain diagram that shows him exactly where my pain is being experienced. That, along with the clinical history that they would take in the office, allowed the clinician and me to have a quite informed discussion about, so what's going on, what are the likely causes of this, what are the likely treatments that would be best for you? What's important about the tool, and so it is feasible to be done, it's been done at Dartmouth Hitchcock in a number of their programs and in other places around the country.

What is important to the success of doing this, in terms of the best practices, I think are a couple of things. First, it would help tremendously if there were consensus on the domains and measures that should be implemented, in terms of patient-reported outcomes and that consensus is now emerging. So, there have been a number…you all and many others are working, and I see consensus emerging, so there doesn't have to be a set of measures that cannot be compared to each other. That will be important for the broad adoption of this. The last thing I think that's critical is that the measures have to be implemented in ways that are useful to both patients and clinicians, that is when they are useful to clinicians, when the pay attention to the measures, the patients then find it really useful to fill out those forms. If you fill out a…if a patient…we just, I'm co-chairing a conference on ACOs and the best practices in accountable care organizations and burdening patients with a lot of questionnaires that are never used by their clinicians will lead to resistance to this particular set of activities. So when physicians…when the information is made useful to physicians at the point of care in providing their care, patients will want to complete those forms and we heard yesterday from Dana Safran, who probably should have been here, that in their early pilots in the alternative quality conduct around patient-reported measures, the patients are getting very excited about completing…about being asked about things that no one's ever asked them. As much as we think we do a good job taking clinical histories, we tend to focus on things that aren't necessarily what are meaningful to patients.

So the last thing is, if you make it useful at the point of care, to the clinician in providing better care to the patient, making better choices, you can then use that same information when aggregated over time or across practices to do the clinical improvement in the practice and to roll it up as an accountability measure for health systems that would be adopting a common set of measures. So, I think the notion that the measures should be meaningful to patients, capturing the domains of care that they really think are important, they should be useful to clinicians and if they are, then I think it will be feasible for us to implement these, because there won't be all the resistance to the burden of collection. So, I'll stop and give more time for discussion, unless you want to jump in with a question.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I think we'll go to the next panelist and then we'll ask our questions. But, we will not give you extra 40 seconds Suzanne; you've got the clock at the beginning.

Suzanne Heurtin-Roberts, PhD, MSW – National Cancer Institute

Okay, thank you. I'm Suzanne Heurtin-Roberts; I'm a researcher at the National Cancer Institute and part of our implementation science team. I would like to state initially that these ideas represent those of the NCI implementation science team and are in no way intended to represent the NCI as a whole. In preparation for this briefing, we were asked to address several questions in our remarks. One question referred to emerging best practices and integrating patient-generated data into EHRs for optimal health management. With reference to this, I'd like to report on a project in which our team at NCI is engaged, called the patient-reported data project for routine health care. Working with UCLA, Virginia Commonwealth and clinical sites in those areas, we're investigating methods to incorporate patient-generated data into routine care, allowing for the meaningful use of this data for mutual goal-setting and planning between the patient and provider. The purpose is to develop and evaluate a mechanism for patients to report on various evidence-based dimensions of behavior and wellness known to be related to risk for negative health trajectories.

It's a three phase study. In phase one we consulted with various stakeholders, including clinicians, researchers, health and professional organizations and advocacy groups. These were convened through a number of meetings, discussions, the use of an NCI researchers wiki called grid-enabled measures, or GEM and town hall meetings to reach consensus on the measures to be included. Final consensus was reached on thirteen measures, covering a variety of health behavior and psychosocial risk factors. Researchers and clinicians developed a user-friendly patient health update questionnaire to elicit patient health data.

Phase two, which is ongoing at the moment, is a feasibility study piloting the incorporation of risk information into primary care settings through the use of the questionnaire generated in phase one. Patients are asked, before a health visit, to respond to brief screening questions about health concerns, such as smoking, depression and anxiety, healthy eating and alcohol use. These are being entered using pen and pencil in phase two, but will utilize electronic data entry in phase three. The purposes of this phase is to determine the feasibility of having patients report on wellbeing and routine healthcare and to learn how different primary care settings can integrate this into their workflow. We also want to learn how providers can respond to patients regarding this information in a manner and time frame swift enough to be of use in the clinical setting. After materials and processes have been developed, piloted and vetted, we'll move to phase three. This will be a pragmatic trial of the capture of this patient-generated information about evidence based risk factors and the use in clinical encounters for mutual goal setting and negotiated plans of action. The trial will be carried out in this match sample of clinical sites forming the Cancer Prevention and Control Research Network, which is a collaborative of the CDC and the NCI.

With respect to real world settings, we anticipate the clinical workflow for this process will vary according to practice setting and according to modalities of obtaining patient-generated data. In this study we anticipate patients will be asked to respond to the risk questionnaire either in the days prior to their visit, or at the beginning of their visit. Responses will be made available to the practitioner before or during the visit, and a set of several algorithms will provide practitioner guidance for prioritizing the data to address first with the patient, then other co-occurring risk factors, and then deciding which elements can be safely addressed at a later time. Providers will be guided in identifying red flags for health concerns in negotiated goal setting and planning with patients and perhaps family and significant others.

We understand that this Committee is especially concerned with HITs role in eliciting and utilizing patient data, particularly in mobile devices. We certainly envision a strong role for mobile devices, but we think we're not quite there yet in terms of scaling this up for all populations and practices. Questions of economic resources, health and electronic literacy challenge immediate implementation of these devices across the board. From our experiences, modality of data capture and use can be expected to vary since clinical settings and patient populations differ, as to patients and health system preferences. At this point, we in the implementation science team are focusing our efforts on investigating the content of patient-generated health data that may be particularly beneficial to patient's health and clinical practice, and exploring how to make use of this in real world, clinical settings. It's not the main focus about the data, not about the technology; it's really about the person's health.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you Suzanne. Neil.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

Thanks. First I want to say thank you to the Committee for inviting me, it's really an honor to be seated in such distinguished company. So, I'm a primary care doctor at Brigham and Women's Hospital in Boston, and the medical director for patient-reported outcomes at Partners. So I'd like to tell you first briefly what we're trying to do at Partners. We launched our effort to institute patient-reported outcomes last year with the ultimate goal of having patient-reported outcomes across clinical settings and across clinical conditions. We went live in March with a subset of patients and clinics at both Mass General and the Brigham.

So specifically the patient-generated health we're trying to capture is quite basic, it's the things that healthcare has not yet captured in a systematic way. So for all conditions we ask a standard set of questions that cover physical and mental functional status, that's quality of life, pain, can you walk up stairs, mood, fatigue; these are all captured in the promised ten. Then for each condition, there are condition-specific questions, for example for bypass surgery we ask about chest pain and shortness of breath. So very basic and very brief, less than five minutes usually. So the patient's answers are converted into a few scores, functional status scores, composite symptom scores and the results are reported to patients in real time, at the same time as their physician. The reports are simple and they show the patient's score, the score trend over time and a reference value, that's based on the rest of the population. So, we do our first collection in the clinic with a tablet, and then on that tablet, the patient selects how they'd like to follow up, whether by phone or through our patient portal. Now, we chose this multi-modal approach because while we'd like to see all the patients respond through the patient portal, not all of our patients are savvy enough and so, from our focus groups, we found that IVR, that people have mentioned before, is the best way to reach our elderly patients. And the call is ostensibly from the patient's clinic itself, so, we're trying to avoid the telemarketer response as patients just hang up the phone, and there's a backstop if people don't reply to the email or respond to the IVR, then a human being calls them.

So the patients can their report right away, and the physicians get the results in the electronic health record in their results manager, just as they would get lab or an x-ray result. The one difference with this is that they have to click on accept patient-generated data. So once they do, the result comes in two forms, one is a PDF report, which is exactly what the patient will see, and that goes in the note section of the EHR and the second bit is that the numerical scores get imported into the flow sheets, so flow sheets are where we keep heart rate, blood pressure, weight information that is tracked over time. By putting numerical scores in there, we can see how the functional status moves over time and by clicking on any of these numbers, you can see a graphical trend.

So, how do we plan to use the data? So, the most obvious way is for the individual patient to use it with their clinician, we're capturing things here ordinarily by history. So now we're trying to do it systematically, because when we do it by history, all the information is trapped in that one clinicians mind, and not necessarily recorded in the record. But now, if we do this in a more systematic way, it can be incorporated into the system, which will be important as we move towards team-based care. The second way to use the data is on the population level, to better direct our care and resources. For example, does back surgery benefit patients with low back pain? We don't know the answer to that yet, so if we can track patient's pain level and functional status over time, we can finally tell what the best care is for patients, not to mention, the most cost-effective care. Third, and I won't go into this much, but these can be used as reportable quality metrics for individual physicians or institutions and finally, I think, individuals can use patient level population data. So, if they're trying to decide on whether to do a certain procedure, what better way for patient engagement than the physician to sit down with the patient and say, "here's how other patients like you did after this surgery." That would be a leap forward, I think, in informed medical decision making and better set patient expectations.

So, take away some implementation so far, I think, as Dr. Fisher mentioned already, the biggest take away so far is that patients love this. So we were worried initially that patients would be confused by the iPads, no, they love them, especially the 80 year olds, and they find them very intuitive to use. Second, we were worried that patients would be concerned about privacy, where is this information going, who's using it; but we've managed to communicate, this is between you and your care team, and no one's batted an eyelid so far. The third is that we were worried the patients would not want to be bothered by entering this information; but, on the contrary, they completely get it and say things like, "these are the questions that I should have been asked all along." I'm noticing that my time is running out, so I will save some of the other take-aways for the questions, but let me close by saying that I think the Committee has shown a lot of foresight and the policy changes they are making here are really having a big and positive impact out there in the trenches, and I think that patient-generated health data has the promise of really transforming the healthcare landscape as we go forward. Thanks.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

John.

John Amschler – Quantified Self

Good morning. Thank you for inviting me to share my views. I got up early, for the west coast today, but, I got an hour and a half of deep sleep last night, who else knows that about themselves. Okay. So, if I get an hour from the Zeo, if I get an hour, I'm pretty certain I'm good still for a full strong day, whether it's working out, anything. So, this data helps me support me through my life, not necessary, I don't…it's not a crutch, I'm not a parasite to the data, it's an enhancement to my life. I'm here representing the Quantified Self. If you can see my data right now, I'm sampling a couple hundred data points a second. Do you know what I'm wearing, can you see it? No, you wouldn't know unless I told you, most people don't know unless they tell me. So, does the – pardon; not yet, I'll let you guess.

So, there's a big emergence out there of people who say, I don't want people to know, I don't want people to see it, it's uncomfortable. No, it's not uncomfortable; we just have to make the user experience matter. It's got to be something that…I design cell phones, when you touch the cell phone, you make a call, what matters is that, I got in touch with Gail, it worked, I don't need to know the signaling, I don't need to know the stuff that goes into that to make it happen. I need to know that I got what I want, it's about user experience. I design chips, I design circuits, I design the stuff that's mundane, and if I do a bad job, you're going to know about the mundane part I do. If I do a good job, you're going to get to call Gail, and you're going to say, "hey Gail, happy birthday, great to meet you, where are you?" "I'm in Hong Kong." Perfect, that was amazing.

So it's really about the experience, it doesn't matter about the device, and if the experience is, wow, there's this guy who has PTSD and there's a researcher who uses a Zeo just to find out what it is, because the sleep study in the hospital is horrible, from what I hear, you're wired up to all this stuff. It gets great data, but it's not about great data for that guy, it's about sleep. Really, think about it. It's not sexy to wear a Zeo headband, I would have brought it with me, but it's at my cousin's place charging right now, so I can wear it tonight as we go out for dinner and drinks and I can sleep; and then if I want, I can get feedback and say, "oh, you know what, red wine makes me sleep really well, but white wine has such a sugar spike that I sleep like crap." So, wouldn't it be great to know that I have a presentation tomorrow and I shouldn't drink white wine. Just something that people can learn, and I have a buddy over in the Netherlands who sleeps like a rock when he's drunk, he gets deep sleep, so he's yelling, he's in college, he knows that going out and getting trashed the night before a big test, it's fine for him. But another friend can't even think about smelling alcohol. So, those are the stories, those are things that matter to people. Think about what matters to you, what this can do for you.

I'm a techie; I'm used to big amounts of data. Your cell phone network's down, is it my cell phone, my design, my piece of software, my piece of hardware that made this be the problem. Big data, yeah. Engineers deal with it all the time. Semiconductors, the chips that go in your devices, without big data of years and years ago, we would never have all the toys we have today to play with. We'd never have all the communications. We'd never have airplanes that are light enough to fly across continents. This stuff is mundane. This is what's important, "hey, how's it going, oh wait, you're not wearing an armband, what's wrong?" I got a body media right here, you can't see it; it's what they use on the biggest loser. It's not a cool device, it's definitely not a sexy device, I'm not allowed to wear this at night when my girlfriend's around; it doesn't happen. Why, because it's more about the experience, it's not about the data all the time.

Statistically it's irrelevant that I don't wear it when I sleep, but I can solve that with something else, I can solve it with a bed pad that has a microphone on it, which, you guys can all imagine what trouble that can get us into. But that can also tell us our heart rate, so you can black it out, you can say, no don't record that time, I don't want that out there, but you can get your heart rate from a simple microphone with an air mattress under your bed. Now imagine if you clench your teeth, if your body temperature goes up and you have a, I forget what it's called, Chilli Technologies water cooler underneath you. We have a world record set by an American Olympian who uses this type of technologies to optimize himself to set a world record for his age group, which I think is 35 to 40, in the velodrome. It's those crazy guys who do 45 miles an hour in a circle, on track, to break the records. Athletes have been using this type of technologies for years. We use…so SARA Wireless has a beat-by-beat blood pressure; wouldn't it be great to understand blood pressure and truly know if does white coat really mean elevated blood pressure, because for me, white coat means decreased. Because I love my doctor, he's awesome, I go in there and it's like chilling out at a bar, there is no bar, but you have to realize what white coat syndrome is, it can dip or it can raise, we have to know the changes.

So, there are a lot of technologies out there. I changed my presentation because a lot of people mentioned a lot of the things I would have talked about. So, my time is up, but get on to questions and let's think about people, not just devices; it's the experience, let the techies figure out the mud, in between everything. Thank you.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you John, and thank you all the panelists, and we've had a wide range of testimony today, and that's wonderful, it gets us all thinking. We've heard about information, it might be solely for the patient benefit, solely for the physician benefit, for mutual benefit, for community benefit and for population benefit. And I think we have to think of patient-generated data in this holistic manner, because we are now introducing a new actor or actors to this very bifurcated, siloed structure, and it's going to be very disruptive and very, very powerful. Because, I think, to John's point, the experience that we have in healthcare helps to build on Judy's point that our confidence should be increased by those experiences, to Barbara's point that it can be used to really enlarge your community of health, to Elliott's point that it can be very, very detailed and germane to care in the moment of care and to Suzanne's point how it can very much embolden a population of health. So, I appreciate the panel's contributions. I'll take the moderator's prerogative and ask a question. Based on this holistic approach, it does seem that there are opportunities for modular approaches to integrating health information, as we see information relevance and mutual benefit as a very common theme through this group. So, I'll ask the panel to comment on this idea of modularity to electronic health records.

Barbara Howard, MD – Child Health & Development Interactive System

So, we think that having modules is really going to be critical to making the kind of content specific information up to date and also to help enhance the experience of the physician through quality improvement efforts. So child healthcare in particular is often left out of the basic structure of EHRs, it accommodates it a little bit, they find a place for vaccines, but by having modules, you can do much more specific work and you can change over time. So one of the things that CHADIS does is that it delivers all of the questionnaires that are recommended by the American Academy of Pediatrics for care. Well guess what, those keep changing and so having a module that incorporates the proprietary, evidence-based tools, as needed, and makes them available instantly to the primary care doctor, makes it possible for the primary care doctor to have all the tools they need, all the time and what we need…only what is left to do, is to make sure that it flows seamlessly into the EHR. So we think that child healthcare is probably not the only example of modular care, but it's a good example of why it needs to be a nimble system and EHRs are not known for being nimble and content specific, and this is something that a module can do, in addition to triggering the decision support for the doctors.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Any other panelist like to comment?

MacKenzie Robertson – Office of the National Coordinator

And that was Barbara Howard.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you.

Elliott Fisher, MD – Dartmouth Medical School

This is Elliott Fisher. I guess I'm not completely sure I understand what you mean by modularity, but if you mean different component…different domains of measurement that can be flexibly structured to meet the needs of a particular patient so they're not bombarded with all of them, absolutely. And the fact that MGH is starting with the promised ten. I'm sure you are all aware of the Promise initiative, it's a tremendously valuable resource that the National Institutes of Health put together, where with computer adapted testing, you do not necessarily have to ask full scales, you can take advantage of item response theory and the way the computer might work, to identify the subset of questions which will most accurately score someone on a continuum for a particular domain of health, and do it efficiently with three questions instead of the standardized thirty, if you get the computer to select the sequence of important questions. So, I think modularity will be important.

I think there is another barrier which we have to think about, which is that there's a strong history of proprietary patient-reported measures which are out there with huge investments on the part of different communities; whether it's cardiologists or orthopedic surgeons. And the use of those proprietary measures they find very valuable, they've got a tremendous investment in that history and they're used to using them in their clinical practices. There would be an opportunity here, if we start to think about collecting…developing ways of collecting the data that let at least some of the places that are doing this collect data in both modules, in the Promise version of a non-proprietary set of questions and say the Oswestry, which would then allow the cross-walking between those modules to capture the underlying domain of health that we're interested in, say back pain, in a way that let the orthopedic surgeons continue to use the Oswestry if they wanted to, gain the value from all their old data, but have others adopt the Promise tools, and be able to compare themselves to all that historical data by the…that's been collected by the orthopedic surgeons. So, I think we have a window of opportunity to think about systematically developing the patient-reported measures that would be used for this in ways that build on the investment that's already been made and make the non-proprietary measures that are now available, broadly available without all those license fees and other things.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you. Suzanne.

Suzanne Heurtin-Roberts, PhD, MSW – National Cancer Institute

In our project, I'm Suzanne Heurtin-Roberts. In our project at the NCI, we sought to assemble a core set of measures that would be applicable to most people, that are based on good, solid science, and that would be useful in a clinical setting. They'd be quick; they'd be easy to use for persons with various levels of health literacy. It seems to me that one approach could be to have one set of core measures that are agreed upon and then the sort of data generation could be personalized according to patient's needs, by use of different modules. But I do think a core set would be very, very useful.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you. John.

John Amschler – Quantified Self

Modularity is key, but again, the user experience is part of that. Like everyone says, don't give the user everything, give them what they need. Well, don't just give them what they need, give them who they need. NASA selects astronauts and they have personality tests. Companies are taking that personality test and trying to mate people with their consumer experience. When I call into the credit card, they'll have my profile and they'll say, okay John only wants to talk to somebody that doesn't say "we're so sorry." I have problem, just solve it, I don't need all the fluff. So they try and match that personality-wise. Imagine using that for the consumer of their medical device; oh, this is a person here and you know what, this overlay has proven to show this, but it let them dig in further in case…in case my mother's looking at it. I'm like, "mom, let me dig it, I can click and look further and further and educate her in the process." So it's really about starting at level you are. If you're an ultra-marathon runner, you don't take six months to train for a marathon, you just go run the marathon tomorrow. You've never run a marathon, you train, you find out the problems. So, it's about keying people under individual self and where they are, rather than just the data. That's the next step, in my opinion.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you. Neil.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

I just want to add, one practical point which is, we are trying to reference a problem list to generate which modules…aside from that core measure, we reference a problem list and get the modules that are applicable for that patient. We found that there's variable use of a problem list across the system, obviously, and it's with variable accuracy. So, if you marry this to patients being able to verify their problem list, I think you'll get a much more accurate picture and be able to use modules better.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Great, thank you. And I think we have questions starting with Eva.

Eva Powell – National Partnership for Women & Families

Great, thanks. Eva Powell of the National Partnership for Women and Families. First I have a comment and then a question. And the comment is, thank you, first of all, for talking about psychosocial elements. As an old hospital social worker, I see that as hugely important in what we're all about. And I think the connection made in the earlier panel, and also in this panel about not just how are we going to use this information, but actually linking this information to clinical decision support is critical. And it makes me think of, actually, something that was said at a meeting I was at earlier this week, that really shed new light on this for me, and the statement was that health literacy is actually a two-way street. Normally we think of health literacy being something that we are helping the patient gain more of; but, it's actually a two-way street. The providers need greater health literacy on what health means to patients, what information is useful to them and how it needs to be presented; and really all the things we're about today. And so, I just say that only as a means of kind of framing this a little differently in understanding this two-way street and some of the cultural issues that came up in the other panel. So my question then, and this is for me connected to the notion of psychosocial data, as well as this notion of health literacy on the provider end, what are the implications for each of you, and I can see them potentially from each of your testimonies, what are the implications for health equity and increasing health equity and decreasing health disparities? Because that's something that we as a Policy Committee really need to work on in Stage 3 and that's a difficult thing. So, if you could impart knowledge that would be helpful.

Barbara Howard, MD – Child Health & Development Interactive System

Well, I'm Barbara Howard, from CHADIS, and I started talking about how the more electronic we get, the more careful we have to be not to leave people out. So, we still have people in the United States who can't read English, but technology can actually help with that, instead of getting in the way, as long as you pay attention to that from the beginning. So what CHADIS does is, it allows multiple ways of data entry, one is online from home on your computer, but another one is through an interactive voice response telephone system and another one is to have the questions read out loud by the iPad and they simply have to touch the "yes" or "no" buttons; and that really gets around some of the literacy problems that are getting in the way, even of paper records. So, I think that the health disparities can actually be helped by systems of care, and can get past language problems. Right now there's some of the practices using CHADIS, out of the 38 states where people are using CHADIS, some of these practices have 137 languages being spoken by patients in their practice. Well, that's a big problem for a healthcare system and an electronic system can help with that, because it can actually manage different languages. So, we have a long way to go, but that as a culture in adopting to these languages, but that's something that can happen, and of course the decision support can be individualized to a cultural or literacy background and the handouts or materials that go to the care portal in CHADIS, can also be individualized to that patient.

Judy Hibbard – University of Oregon

May I just …

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Yes, go ahead Judy.

Judy Hibbard – University of Oregon

So, this is, I think, a really important question, and we do see that disadvantaged populations tend to have lower activation levels. And the other thing that we've learned is that people, who are low activated, have had a lot of experience with failure with managing their health or with getting what they need from the system. And so what we've also seen is that people tend to get treated within the healthcare system as if they are more activated, and so the result for the low activated is that they get set up for failure; they get too much information, too many changes recommended for them and they can't follow through. And setting people up for failure essentially keeps them in the position that they are, where they don't become engaged, they don't become active with their health. So, by not really understanding the patient and who they are and what their needs are, we really are contributing to maintaining those inequities that are there.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thanks. And Suzanne, I think you had something.

Suzanne Heurtin-Roberts, PhD, MSW – National Cancer Institute

Yes, Suzanne Heurtin-Roberts. I'm an anthropologist and also I have a background in social work so, starting where the client is, which is the background in social work, I think that we don't want to become fixated upon the data or fixated upon generating the data, although, God knows, that's important, but we don't want to lose track of, what are we going to do with it afterwards and how are we going to use it. And the thing that we're trying to do, and we're putting this together in planning phase three of our project, is how do we facilitate the negotiation, and it's a negotiated activity, between provider, between the patient and the family to develop goals, to develop plans for what's going to come ahead. And this has to be negotiated in terms of the patient's cognitive self, their social self, their cultural self and their economic and physical environment as well, or it's not going to work. We really do need to tailor things.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

So, from the primary care perspective, the biggest determinant of whether someone gets the mental health resources they need is their insurance status, and that's tragic, I think. And what we've seen, when we rolled this out, the stickiest portion of this is with primary care clinics that are not patient-centered medical homes. So there's a big difference in their response to rolling out these patient-reported outcomes. The biggest concern of…sorry, Neil Wagle…

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Neil, go closer to the mike.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

Oh, oh yeah. The biggest concern of the non-medical homes is that they're going to find…it's going to be revealed, because we all know that it's the case, that a huge percentage of their patients are depressed, and then, you know, how are they going to handle that information, we don't have the resources right now to deal with that. On the other hand, the medical homes have those resources in place, and so they're really excited about this data, because, as you're saying, how is this going to help our decision support? You get this data that your patient's depressed or their mental score is low, and it triggers automatically a referral to the clinical social worker, so…

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thanks Neil. Go ahead John.

John Amschler – Quantified Self

Hi, John Amschler. Honestly when you said the term, I had to look it up on Wikipedia to make sure I was looking at the right quest…going to answer the right question, which kind of baselines me to it's not about what the level of access is, I think you have to set a low bar, this is the minimum we'll allow. It's shocking for me to hear that mental health is based on your insurance. So, if that's the low bar that we need to raise, raise that. We have enough systems that we can pick out individual things and raise it, and give people access to the technology, access to the knowledge. And it's that access for some level that's going to help and then there are people who don't realize that access. So we have to figure out how to help them realize there's the access, or have advocates for them. So, the inequality, I'm okay with the inequality, let the sprinter sprint, let Larry Smard do his stool test to find out that he's about to have an event, and that he just found out he has Crohn's and he's treating it beforehand, let him do this. But make sure you talk to him to understand what the low bar should be for the future of health when these things are implemented.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

We have about fifteen minutes left and we have three questions up, so we'll go to David Lansky.

David Lansky – Pacific Business Group on Health – President and CEO

Thank you. I want to come to the purview of this Committee around the tools we have within the meaningful use program in particular, and one of them is the quality measurement approach. And in particular I want to ask Neil and Elliott specifically; assuming that the models that Dartmouth and Partners are using to capture patient-reported outcomes is a desirable approach, and we want to use meaningful use to drive more of that; as we look at Stage 3 and the quality measurement system, one thing that's been surfacing…there is, as you may know, a total knee replacement draft measure floating around. One of the issues that surfaces is, and Elliott you spoke to this, do we need to create…do we need to impose as a matter of the Federal program, standards that the EQ5 is in but the something else is out, the Harris hip is not in the program. Do we have to say, here's a list of qualifying instruments which can be used for the purposes of the meaningful use program, and if so, is there any corresponding implication on the EHR vendors certification requirements that they have to be able to capture a set of sub-scales or a single scale or raw data.

And what I'm trying to think through a little bit is both the governance question of who makes those decisions, is that CMS is going to write a reg saying these five instruments qualify and these six instruments don't, or can it be more open-ended. The proposal we've surfaced for discussion was that there be a set of qualifying assessment instruments for a set of priority conditions, that the EHRs be certified to be capable of capturing summary scores, there be some parameters around a protocol that says, within thirty days preoperative and ninety days postoperative, but there are some windows. So, as you can tell, what I'm struggling with is what's our role in prescribing a set of assessment tools and a set of methodologies for this program or can we back off of that and still achieve the goal of driving more meaningful users to do the kinds of things both of your organizations are doing. So if you just walk through what your best recommendations would be to us of how to structure a program that would stimulate adoption that would be great.

MacKenzie Robertson – Office of the National Coordinator

Excuse me, sorry. Leslie, I just wanted to point out, lunch is at 12:30, so you have more time.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Oh, thank you very much.

Elliott Fisher, MD – Dartmouth Medical School

Good, so I'll talk for twenty minutes…no

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Not so much.

Elliott Fisher, MD – Dartmouth Medical School

David, those are really great questions. This is Elliott Fisher. I think the…I would think we want to be considering standards for what those instruments should be, and those probably would include, I'd nominate things like non-proprietary, it wouldn't cost and arm and leg, people would have to, if they want their instrument included under…and I am intrigued by the huge investment we've made in Promise, and the question of whether, if you want to use another instrument or have its adoption, you're going to use it for quality measurement, say you're Oswestry if you're a knee sur…back surgeon, knee surgeon, why am I confused? It wasn't the hour of sleep. If you're going to use a specific proprietary meaning to track improvement to measure quality, it should be cross-walked to the Promise scales, so there's some nice way of building the modules, the measures that we have available, so that if we're tracking improvement in a physical domain or a set of symptoms scores, that it should be linked to the emergence of computer adaptive testing, IRT if you're including those scales in the…what will be the national index of items for adoption under CAD technology that would make it much less burdensome for patients to use it.

Something like that that has some set of standards and a cross-walk that markedly expands the utility of this data rather than further silos it. That is silos if we have thirty people doing knee surgery using different instruments, we can't compare their results, purchasers can't know really how to compare the outcomes in two different practices.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

This is Neil Wagle and I totally, I totally agree with that. I think using the non-proprietary tools is better. And I will also say that while I hesitate to really narrowly prescribe what the measures are, I think the more we do that, the easier it is for institutions actually to move in that direction. Because it can be paralyzing for an institution to say, what's the thing we're supposed to measure, and I don't want to pick wrong, because then I can't go back. As Dr. Fisher said earlier, we can see things sort of moving in a certain direction on a case-by-case basis. I think the degree to which you can anticipate which direction things are moving, and then say, this is the standard; that's valuable to everyone. And it can be in a staged fashion, say with some core things first and then other specific things later. I also think that it will be tough, but the more you can say to electronic health records, this is what you need to be able to report, I think that's difficult, but if you telegraph it, in advance, I think that would be better for everyone.

Elliott Fisher, MD – Dartmouth Medical School

I really do, this is Elliott again. I really do believe that we should have standardized…if we're doing quality measurement, you have to do it by comparing using the same scale, using the same set of measures. So, CMS is probably the right one to decide, at least for…because they're so engaged in so many of the measurement activities. But, I think the proliferation of more measures and saying if we're going to be measuring quality, we have to be measuring it using a standardized set of tools. And if you want to use other tools, they have to be cross…I'd nominate, go ahead, but then cross-walk them so that you can be compared to the standardized tools.

Neil Wagle, MD, MBA – Brigham and Women's Hospital and Medical Director for Patient-Reported Outcomes at Partners

Sorry, this is Neil again, I'll just add one more quick thing, which is, imagine the power of the data set if everyone's using the same scale and we can aggregate that data and then say, this isn't just Partners data…Partners information about how people responded to a knee replacement, this is the nation's data. That's really powerful.

David Lansky – Pacific Business Group on Health – President and CEO

Thanks.

Barbara Howard, MD – Child Health & Development Interactive System.

Barbara Howard from CHADIS. Another comment on that though, and that is that often the measure of quality for adults isn't going to be the same as for children and if you get too general a measure, you end up having nothing of value. I would also want to reconsider whether a summary score is all you want to require people to accept, because I think often it's in the details that you actually see things that are amenable to change, not just a summary score.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Great. Let's move to the next one, I think it was Charlene.

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

Yes. I actually wanted to talk a little bit to John and then kind of bring it back to measurement. John, when you talked about the experience, the things that you're doing are self-regulating, you know, you self-regulate, and a lot of this in terms of transforming healthcare is going to be about increasing each of our accountability in terms of doing the right things and self-regulating. So when we think about measurement and accountability in patient-reported data, there's been examples of patient report cards out there and other types of techniques relative to, okay, how am I actually doing in managing my health and staying on the care plan.

So where does that fit into this process in terms of patient-reported data, is it the data that you capture from the monitors, is it the data that you say, okay, I'm actually taking my, again there's tons of sensors out there, I'm taking my medications like I'm supposed to. So where does that fit into this process to really kind of help us close that loop and again there's probably experience each of you have had in that area and that would be informative.

John Amschler – Quantified Self

This is John Amschler again. It really depends on the user. There is a friend of mine who had lost about 30 pounds by I forget the Japanese author's book's name but what he did is he simply recorded down by hand what he wanted and what he realized is you know what? If I eat my son's French fry, just one, I have to record that. So, his motivation was, is this French fry worth recording it? If it was a piece of chocolate cake, yes, it was to him and I forget if it was chocolate cake that was his thing, but stuff like that. So, it's really the individual thing.

When I was training for running I didn't tell anybody because talking about running is demotivating for me because you're training so much, you're doing it all the time. I wanted to have a different outlet. Other people when they're training for a marathon they talk about it all the time because they get the motivation. So, there is no one blanket, but the nice thing about data and technology is we can have a personality wrapper. We can have a language wrapper. We can have a time of day wrapper. We can have all these different wrappers and overlays and all this technology and so it really comes down to a lot ethnographical work where people study does this motivate you, does this not, which means we need a lot of people in society to say yeah, I'm willing to do that because, you know, it's really hard to talk to my mom about data, she's a touchy-feely person. So I have to abstract that, I have to put it into her language. I need a translator.

So, I'm not sure if I've directly answered your question, but I think with computers and the simplicity of handling the complexity we can figure this out and we're going to get it wrong. Websites get it wrong all the time. We put five different websites out there at a time and decide which one gets more user retention, which one gets more repeat visits and then we say that's the best one. We never thought it was going to be, but that is so let's use it and then later, they do it again and they keep iterating. So it's iterative, it's definitely going to take a while; it's not going to be here you go people, because people change.

The Facebook generation is already looking at us saying why are you guys having this conversation just do it. It's really…we should have a lot of people under 30 in here looking at it and going…Nikolai, yes, let's put this out on my Twitter feed, let's do this, it's part of his life. I have another great friend with Crohn's he doesn't want to deal with it, he's my age but he's also a software guy. He could solve this problem but it's not the problem he wants to solve. So, it's individual, let's use the technology to help us get personal interaction.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Okay. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, we've had lots of pretty wide-ranging conversations here and I guess I'm seeing an emerging pattern of sort of an old insight of data gets better through use and whatever the loop is, the more it gets used the better it's more likely to get whether it's a list of warnings about how this patient had adverse reactions or, you know, it's a problem list, and if we use it, it gets better and if we just write things in it and no one ever looks at it, it doesn't get better and if we have all this data that's being collected about someone it's just being collected and it's just a fire hose and maybe it's not really useful for improving care.

But I also sort of feel like we're doing this in kind of a culture shift time. So, to say just do it is harder than just, you know, you can't…if we could just do it we would just do it. And yesterday we talked about kind of a shift to a data culture to actually being sort of savvy about using data. So, you've all sort of been struggling with this in different context. So, do you have any advice for us about one or two key things that sort of helped shift the equation out of can't do it to can do it?

M

Well, our experience with accountable care organizations may be useful, that is where you start to put financial incentives in place that open the door for provider groups to do what they might have hoped to do for which data will be absolutely critical. I mean, the last two days of conversation a few blocks down, really center on the use of data to help disadvantaged populations in Camden, New Jersey, you know, to help the providers there identify patients who are at risk and really intervene effectively and all of…so when these provider organizations become responsible for improving care, they know they can't do it without data. So, there's something about engagement, the data isn't being collected for the purpose of the data, the data is being collected to help people do what they really want to do under a new set of incentives that says by the way you should do it. And if you don't we'll try to embarrass you.

So, I think making the data useful for purposes that are meaningful to the patients and the docs in a new payment environment so that linkage of…and I haven't quite thought through how that fits with the Meaningful Use criteria, although I am convinced that the only way we're going to measure the effectiveness of patient centered medical homes or accountable care organizations is by showing that they're making people better on the things that matter to them. So, please do include them under Meaningful Use 3, because I think good quality measures will be…will lead to…and people seeing that on the horizon, oh, it'll be in Meaningful Use 3 we'd better get going now.

It might be in Meaningful Use 3, I mean, they're all starting to say…lots of places they're talking to us about, gosh can we start piloting patient-reported outcome measures, because we want help, we know it's going to be coming someday, so we have probably 20 places that we're talking to around the country trying to say can we join you just because we want to because you guys might expect them to? And they know it'll be useful under new payment models.

Barbara Howard, MD – Child Health & Development Interactive System.

Barbara Howard from CHADIS. So, I'm not sure that I agree that data gets better with use all the time and part of the reason I'm saying that is because what's happening in pediatrics is that there are more and more, and more requirements for what people should do during the visit and the patient is getting lost and their chief complaint is getting lost. So, one thing I'd like the committee to consider is an exit strategy for some kinds of data. So, for example, right now in Maryland everyone is required to have lead screening whether they have any lead risk or not, well that's a huge waste of resources but you can't seem to get it out of the regulations. So, I think it would be good if you could figure out a way to be able to find out whether the data served a purpose, made a difference and then get rid of it as a regulation if it doesn't.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Okay, Westley Clark?

H. Westley Clark – Substance Abuse & Mental Health Services Administration

I want to thank the panel for their very interesting comments and I want to thank you also for your reference to behavioral health. From SAMHSA's perspective behavioral quality measures are going to be essential to overall health and it's important for us to keep that in mind. So, as we move toward team-based care do you have a better view of how we can use data and technology to promote the integration of behavioral health in primary care and in healthcare in general? I know Neil made reference to the lack of insurance but you're from Massachusetts, right? And you have an insurance structure that in a sense should be facilitated in the availability of behavioral health care yet you suggested that the differentiation and access to behavioral health services based on reimbursement. So, back to the question. How can we facilitate the integration of behavioral health and primary care in a team-based focus?

Elliott Fisher, MD – Dartmouth Medical School

Well, this is Elliott Fisher, I only have one hammer.

M

But there are a lot of nails.

Elliott Fisher, MD – Dartmouth Medical School

Global payment. I do think there are … you know, what we are observing in the emergent accountable care organizations who become responsible for a population under a global payment model is that they quickly recognize that behavioral health has to be at the forefront of what they're trying to accomplish, because of their well-recognized, you know, everybody recognizes that patients with behavioral health comorbidity, you know, as a co-existing condition are much, much more expensive and if there's a global payment component, and you're being measured on quality they're not going to be as adherent on their quality measures and they're going to cost you a lot. So, the emerging practices in the…you know, I think of the…several of the panels with sessions that are running right now are about exactly that issue. How do you do integration across medical and behavioral health issues and data will be critical. I also have to say I'm afraid I got 10 more minutes and then I do have to go back to a session that I'm supposed to do over there.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Fine, all right, Barbara and then we'll get to Hugo and Floyd.

Barbara Howard, MD – Child Health & Development Interactive System.

Barbara Howard, CHADIS. Well, what CHADIS is about is integrating behavioral health and it does it in a couple of ways. One, is it provides the validated screening tools that put the result that there is a behavioral health problem right in the face of the provider because we know that providers intuitively don't pick up on mental health even disorders much less problems and so part of it is to have universal screening with a validated tool that puts the results there.

The second part is give the clinicians some tools for dealing with it because clinicians are people and they avoid doing stuff that they don't know how to do and I think a third part is that technology really has an opportunity to use some new technological tools for expanding where care can be delivered. So, telepsychiatry turns out is probably as good as in person psychiatry and some things like cognitive behavioral therapy can be performed using on-line systems that could be delivered right through the same system that the patient is using to give their patient-generated data.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you. Hugo?

Hugo Campos – Patient Advocate

This is Hugo Campos, and so mine is not as much of a question as it is a comment that I would like to make on the importance of user or patient collected data such as the quantified self as an emerging practice. I am a patient living with…I'm a chronic patient. I want to put it in the context of chronic disease, I'm a patient living with cardiac disease and I have an implantable defibrillator and I do track a lot of bits of data about my health and to Charlene's point earlier or question, this is…what I'm after is more a sense of self-awareness and a realization whether or not I can prevent or reduce the frequency of some of these cardiac arrhythmias that are very common in my situation.

So, I do have Zeo and I track the quality of my sleep as well, I have a Fitbit which I use to track my activity levels, I know for example we all probably here know that we should be taking at least 10,000 steps every day, but do we do that? I can tell you that yesterday I walked 15,000 steps and the day before I walked 30,000 steps. I also track my mood and I also track my blood pressure levels on a regular basis with a device that connects to my iPhone and my iPad. I also track my weight with a WiFi scale.

So, the whole idea is, for me and the value here, it really is for a patient living with a chronic disease of such as I, it really is to be able to paint a high resolution picture of my health and change behavior and engage and I think that this is really where the quantified self as a movement has such an incredible impact and it has had in my own personal life. So, I'm sorry if I'm not following the format and not really providing a question to the panel but I felt like it would be an important point to make for the committee as well. Thank you.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

You also have data from your implantable device. Where does that go?

Hugo Campos – Patient Advocate

Well, I was …

M

That's a loaded question.

Hugo Campos – Patient Advocate

That's a loaded question. I was holding off on that for future conversations, but what's ironic about all of this is that the data…the implantable device that I have that is wired into my heart is capable of wireless telemetry and that data goes to the manufacturer of the device but it is not shared with me. I have absolutely, as a patient I have no access to the data and this is true for all 600,000 Americans who receive pacemakers, implantable defibrillators and implantable loop recorders every year in this country…and some of these medical device manufacturers hold siloed networks or databases of data with sometimes half a million of these devices with live implants throughout the world and this data is not shared and I think it would be incredibly valuable not only on a personal level but on a much bigger scale for post-market surveillance of these devices, I don't want to digress, but in any case, thank you.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thank you, John?

John Amschler – Quantified Self

I'd like to answer the question you didn't realize you asked and to go back to the shift how do we move from what we were to where we're going? The business models of these implantables, their business model isn't to share, it was created years ago, their business model is to mine that data, get new products so they can keep innovating. Trust me every engineer who looks at those cardiac arrhythmia devices, anyone who is mission-critical typically they're in a for a passion so they're not going to let it fail. People want to see their source code…I design hardware, I've worked in source code, some things shouldn't be released.

Your data I think you should get. We talked about this yesterday at NASA Health over at Kaiser; yes I think you get it. But should you get it for free if it costs them a lot of money to create a system for that? No, somebody should have to pay for the system to get your data if they need a system. If it's as simple as here's a disk, there you go, go for it, you should absolutely have it. Should they interpret it for you? I don't think so. We have a problem in the U.S. we don't pay for our devices. I didn't pay for this cell phone, it was subsidized. I paid, what $200 for an iPhone, it really cost $500 to manufacture and get everything and…great business models to wrap it around. If I'm in China, if I'm in Korea, if I'm in Japan they save their money and they buy their device and they treasure it. The devices that we put in are subsidized by their future researchers. They put off cost so that it's more affordable. So we have to understand the business aspects of this to realize how can we do this

My personal thought is you should absolutely have your data but if the data coming out lets their competition come ahead and that company goes away, ask yourself is that better or worse for you, is that new device going to help you in the loss of those jobs going to hurt or not?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Right, thank you, John. Russ?

Russell Leftwich, MD – Tennessee Office of eHealth Initiatives

As a counter point and word of encouragement I sat at the lunch table at the HL7 meeting fall 2 years ago with three gentlemen from three different cardiac implantable device companies who were there to try to figure out a way to interoperably share the data from their devices which were all different. So, maybe it's not all policy that prevents it from being shared.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

That's great, thank you for that comment. Do we have any other questions or comments from the panel? Josh?

Josh Seidman – Office of the National Coordinator

I was wondering if perhaps Elliott and Neil, and maybe Barbara could talk about the integration of the data into the clinical workflow when you have done it. So, how does the data flow from, you know, patient survey into the instrument into the EHR and then into clinical workflow?

Elliott Fisher, MD – Dartmouth Medical School

Dartmouth's experience when they had their original self-built, self-constructed EHR was that it flowed in seamlessly and beautifully into a useful display for clinicians. During the transition to a new electronic health record which you can go look up on-line it is no longer seamless or easily displayed in a useful way to clinicians. There are six different windows they have to click through. The data…the collection of the data in the workflow is still perfectly fine by the patients or in the office practice. The challenge is in integrating the data into a display that is really useful at the point of care for the clinicians. And it's not at the top of the list of the vendor with whom they're working to have those displaces created that are useful to doctors.

John Amschler – Quantified Self

Yeah, so I think that workflow is…the workflow is the biggest fear of clinicians in adopting this and so we got a lot of pushback as we were trying to implement, this is going to destroy our workflow, our MAs are going to be too busy. We managed to use design elements to fix that problem and I think very quickly after implementation those concerns went away. Using paper is difficult because you have to transcribe that information and that takes extra work. We have connected these tablets, these iPads to a number of systems, they connect to the scheduling system and the clinics are able to tell the system these are the patients we want to include for these different reports and then the iPad screen is automatically populated with the names, they can just select them, and they hand them out to the patients. Patients enter the data it goes directly to a third-party vendor that we've contracted with, Quality Data Management, Gene Nelson works there, and they aggregate these multiple streams of data and produce instantaneously a report that gets fed into our electronic health record both in terms of the PDS and the numerical data flow, and then the last thing is that the doctor does have to accept the patient-generated data.

Barbara Howard, MD – Child Health & Development Interactive System.

Barbara Howard from CHADIS. So, one of the efficiencies is the data is collected from home on-line and that makes a big difference when they haven't done that doing it on a tablet in the waiting room is the next step. Currently the clinician has to…either the clinician has to log into CHADIS to get the results and copy and paste them but we're fixing that with integration, that's part of why we're excited to be here, because we think that going one EHR at a time for that integration is a big problem. The other alternative is for an office staff member to have done that before the visit and basically copied and pasted the results into the record, but you can also have a single sign-on that allows basically, while in the EHR to also open CHADIS, see the results and their very user-friendly format as they are which is also interactive.

One of the things I'd like to say about that is that we don't want…we want to focus for this group not just on sending data to EHR but the EHR being able to communicate back because without that you lose a lot of the decision-support functionality and things that are necessary for quality improvement.

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Great. Do we have any other questions from the group? Wow, super, all right, Paul over to you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, and I want to thank the panel for a wonderful job. Since, we're 15 ahead, why don't we reconvene at 1 o'clock, great, thank you.

MacKenzie Robertson – Office of the National Coordinator

Operator, could you please open the lines back up?

Operator

All lines are now bridged.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, welcome back after lunch. So, we had a wonderful morning of opportunities and potential benefits and as we started out we said, well there are these opportunities, there are also some challenges and issues and in this second part of the hearing we're going to talk about some of the challenges, but this is a half full challenges, so that we're going to understand some of things that are clearly things we have to wrestle with and if we don't face them head-on then they'll never get solved and we still won't make progress.

So, in this panel we're going to be looking at some of the policy implications of some of the challenges that were raised even in the first panel, because it's got to be integrated in workflow, somebody has to look at the data, somebody has to do something with all this data and how do we do it in a way that benefits patients and doesn't overburden already burdened providers. So, we have three distinguished guests on this panel to walk us through that. And we're starting out with…who is starting out? In order on the schedule it's Deven. So, Deven's going to talk first.

Deven McGraw – Center for Democracy & Technology – Director

Okay, great, thanks Paul and thanks to the committee, Workgroup members, members of the public. My testimony just so you know is based in large part actually on my experience in serving on the Robert Wood Johnson Foundation's Project Health Design Regulatory and Assurance Advisory Group with the Law Firm of Manatt, Phelps & Phillips, as well as baseline knowledge that I have of HIPAA regulations and I guess a few general impressions thrown in there as well.

I'm not going to go into detail about the details of the project for Project Health Design you're going to hear in a later panel from Patti Brennan, but what's important to know is that in each of those projects the grantees are collecting patient-generated data and much of the data is what are called observations of daily living. So, it's not data that is always customarily thought of to be included in clinical workflows but in fact in each of the projects the information is being incorporated in clinical workflows in some way shape or form but its different based on the project and the type of data that's being collected.

One of the other things I want to say from the start though is that the comment that was made on a previous panel about how we're trying to change culture is absolutely true and how that translates in a sort of legal issue and policy context is in part about if you want…if providers want to do this because they understand the value proposition there are ways to make it happen and there ways to deal with the legal risks that might be sort of part of the equation.

If you've got a provider that isn't interested in doing this and doesn't see the value proposition, the privacy and security issues will be the obstacle on the top of the list that is often cited for why this cannot happen. So, it's a little bit of where there's a will there's a way because they're very few…in fact there are no hard-core legal obstacles that I know of that say I cannot do this because x law prohibits me from doing that. Again, depending on what kind of data flow you're talking about. I'm not aware of any. Maybe Chad will have a different response but I doubt it given that I've seen the white paper and it looked pretty much the same.

So, one of the things that the Project Health Design Grantees had to confront head-on was the issue of potential liability for patient data coming in and needing to sort of be able to deal with it and the set of questions that the providers had and the providers participating in those projects had were not dissimilar to some of the concerns that have come up in panels today. What about timeliness? What if I don't see something in the data that's really important and that I should have responded to? What if my response is inadequate? What if I triage who looks at the data and my nurse or my health coach who is reading the data first doesn't pick up something? Am I going to be liable for the failure to respond to it appropriately?

Volume of data -- the data tsunami, right? Don't send me all this stuff if I can't manage it appropriately because I am ultimately going to be held responsible for something that comes into my practice and that's absolutely true. And then the last question is how can healthcare providers trust the accuracy of patient-generated data? And the trick is that professional liability is about whether you followed the standard of care which is determined by professional custom in an ever evolving clinical evidence-base.

In a circumstance like this where we still have…were models of care, where patient-generated data are sort of routinely incorporate and when I say patient-generated data I mean, again patient-generated data include the oral responsive of a patient during an office visit, right? But we're really talking about sort of routinely collected and routinely transmitted data.

We don't have a lot of models of care out there to provide examples and we haven't had them for so long that we have a sort of well-developed sort of standard of care from a liability stand-point that we can point to and say you should do x-y and z. So, some of this is really quite common sense and is really about setting reasonable and realistic, and workable expectations on the part of both the clinical care team as well as the providers in terms of what data comes in and what data actually comes into the clinical workflow and then the secondary decision about which of that data needs to be in my EHR, because it's not the case that all the data that comes in necessarily needs to be part of the electronic health record documentation, which is really a legal document that the provider uses to justify care.

So, certainly if you make a decision that is based on patient-generated data you were going to have to document that and have it be part of your legal medical record. But if the data is used in a different way it doesn't necessarily need to come into the EHR, there are definitely different ways to do that and so the basic set of questions that the grantees answer…were along the schematic of what, how, where, who and when. What data is coming in, how is it coming in, where is the information collected, does it flow into the EHR and under what circumstances, who is going to look at it and how often or when are they going look at it? And so, I'm jeez, how did I already get out of time, but I did.

I mean some common threads, I mean, again, for each of those projects there was a different purpose for different type of data being collected and different arrangements being made but all the data did come into the clinical workflow in some way, shape or form. The way that it got integrated into the electronic medical record if at all was different really for each project, but some common threads are absolutely there was a plan in place for each project, here's how we're going to manage the data coming in and what we're going to with it.

If it wasn't going to be viewed by the provider the person who did view it was trained to know what to look for and what to alert the provider to. Patients were told not to send emergency information through a personal health record for example and they used judgment again about what information was going to come into the EHR or not. And so, I'm happy to answer questions about the legal aspects of those projects and other parts of my testimony during the question period.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, thank you Deven.

Prashila Dullabh – NORC – University of Chicago – Program Area Director for Health IT

So, thank you for the opportunity to testify. Today I will be discussing findings from an ONC funded study assessing the use of on-line tools to capture patient-generated data with the goal of improving the quality of information in the medical record. Before I begin I'd like to thank Geisinger Health for collaborating with the NORC team on this important study because without them this would not have been possible. So, we began the day today with a presentation from RTI on patient-generated health data. The study that I am about to give testimony about gets into one of scenarios described in the background paper correcting, updating patient information. So, that's what I'll be describing.

Our project has two phases. Phase I explores the current state of the field, specifically the approaches that healthcare organizations are taking to encourage and then process patient feedback. And then Phase II involves collaborating on a study with Geisinger Health where patients are encouraged to review and provide feedback on their medications in advance of their doctor's visit. So, study data has been analyzed as we speak using a mixed method approach meaning both qualitative and quantitative. However, preliminary results suggest the favorability of including patient feedback to achieve accurate and complete medical records.

To summarize there are 5 important findings coming out from the NORC research and I'm just going to go through each one of them. Finding number one, patients are eager to provide feedback and they can provide useful and accurate information through an on-line feedback mechanism. So, the currently ongoing Geisinger pilot involves two primary care clinics in 5 months 866 medication feedback forms were sent to patients 35% of these forms were completed and submitted for review by pharmacists. Based on a preliminary analysis of 139 processed forms 257 medication changes were made by the pharmacist, so at least one change per form submitted.

Furthermore findings from the patient focus groups suggest patients see many benefits in providing feedback on their medications including the ability to track their medications more easily, being better prepared for their doctor's visits which enhances the communication between the provider and the patient, and allows the patient to take a more active role in managing their health.

Finding number two, processes for patient review and acceptance of patient-generated data will vary. So, our research shows while some healthcare organizations send patient feedback directly to the doctor most have established a triage function where an appropriate individual such as a nurse, pharmacist, case manager or a medical records professional reviews the patient input. So, this triage process appears to support more efficient and effective processing of feedback.

Finding number three, processing of patient-generated data may involve both software and human intervention. So, as more patients become familiar with the EHRs and as the use of new communication tools increases interactions between patients and providers about the content of the medical record is also likely to increase. Systems will be required that can scale to meet these needs. In this phase of the Geisinger pilot a pharmacist is reviewing all patient feedback. In subsequent phases of the project Geisinger will assess the feasibility of implementing decision-support to create efficiencies in the medication feedback process that will allow them to process a larger number of patient requests for changes.

Finding number four, the NORC research shows there may be different ways in which patient-generated data can be integrated into the medical record. In the Geisinger pilot the patient-generated data is adjudicated or reviewed by the pharmacist. Actions relating to the review and processing of the patient feedback are recorded and stored in the electronic health record. In the future it is anticipated that all patient input will also be stored in the EHR.

In our review of the MyChildren's portal in use at Children's Hospital in Boston we noted a different process being used. In this case patient-generated data is unaltered, clearly marked as patient provided and…alongside the patient provided data.

Finding number five, the Geisinger pilot suggest acceptance of an on-line patient feedback system is more likely to work when there is a support of on-line health environment. So usage data from the two pilots indicates that on average 30% of patients at each sites are active users of MyGeisinger and then in patient focus groups most patients expressed lots of satisfaction with using functions like scheduling, requesting prescription refills, reviewing test results.

Many patients noted specifically that secure messaging to physician facilitated an ongoing dialogue with their providers. And patients indicated that the responsiveness of Geisinger physicians to secure messages and other on-line communication was an important factor contributing to the use of these on-line tools. So, further research studies including pilots in different clinical settings should be undertaken to generate more evidence on best practices and metrics for processing and incorporating patient-generated data.

Our experience with Geisinger illustrates that providing opportunities for communication is a necessary but not sufficient first step. Finding from the pilot suggest that a well-structured on-line environment utilized by cooperative and conscientious community of healthcare providers can lead to better data quality in the EHR. So, additional details of my testimony are available in the written form. NORC welcomes your feedback on this important topic and is happy to share additional materials that we have generated from the study as it evaluates requirements for subsequent phases of Meaningful Use. I thank you again for this opportunity.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, thank you, Chad?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Thank you again for having me here. It's quite an honor. I'm a healthcare and medical liability defense attorney. So, I typically counsel and represent physicians, and healthcare institutions, and what have you. So, I might be a little bit biased just as a note. My practice as a lawyer really has honed in on the issue of many of the unexpected consequences that flowed from early adoption of EHR and other forms of HIT and I believe there are some lessons learned from the medical liability world about cases that came out after the adoption of the EHRs that might have some applicability when we're talking about the adoption of this new technology. I have some caveats like any good lawyer, liability cases look backwards in time so we're talking about fairly cutting edge and forward thinking issues in terms of patient-generated data. I did my due diligence yesterday and checked again in the case law. I can't find any case across the country having to do specifically with patient-generated data.

The other thing I want to say as a caveat is the legal world does not deal in absolutes. What we have is a finder of fact which is a jury and so the parties are making arguments about, you know, what is reasonable in the circumstances and in the clinical world what we're talking about as Deven said is the standards of care. The only thing I would add is that a great piece of how we're establishing the standard of care is we hire experts who get up on the stand and tell the jury what the standard of care is based on all of these other things. But you might understand because of this there is a very wide range of what might be considered a reasonable use of patient-generated data.

Now as I see it the first liability hurdle for a patient-generated data deals with the clinical management of multiple and discreet sources of data of which patient-generated data of course is one. This is much like the state in most major healthcare institutions where you might have 5 to 10 separate EHRs which are not necessarily at this point interoperable. The core question is, you know, the clinician always runs the risk of missing critical data from a discrete source which could be like a patient-generated data entry if it's not teed up for them when they needed at the point that they need it whether it's incorporated into the EHR or not.

Now, medical liability cases suggestive if relevant medical information is contained in the data source then the practitioners are going to be held responsible for either actual or constructive knowledge of that data and that's particularly so if when that data is reviewed it would give rise to a duty on the part of the clinician to act on that data. Constructive knowledge is a legal construct as it sounds and since the law imputes you should have known a fact if you were reasonably diligent in discharging your duties i.e., I gave you this set of data, you should have reviewed it, if you had reviewed it you would've seen this fact an acted.

Of particular concern would be critical values, contraindications to treatment, emergent situations and incidental evidence of serious conditions such as cancer. We already see this disconnect in medical liability cases where such relevant critical medical data is not effectively communicated to the clinicians and often times due to technical limitations. In the medical liability world however the inquiry is generally geared toward finding an individual who is at fault despite the evidence of systemic problems.

There are two cases that had to do with early adoption of EHRs which came to somewhat opposite results. In Nebraska there was Breeden v. Anesthesia West and in Oklahoma Johnson v. Hillcrest Health Center, it came out the same year. Interesting thing about this case is that it had to deal with a very simple hybrid HIT environment. You essentially had an electronic health record and a paper process that was still existent and concurrent at the same time.

In the Breeden case an anesthesiologist failed to look in the EHR and if he had he would have noted that there was a contraindication to providing anesthesia. Unfortunately, he provided anesthesia and there was undue outcome to the patient. The Breeden case went to court on the question of whose duty was it, the nurse to alert the doctor about this contraindication or was the doctor under a duty to review the EHR that had been put into place and the court found that in fact it was the physicians nondeligible duty to look into the EHR because it had been provided as a data source.

Johnson case goes exactly the opposite way; it basically says that it was the nurse's duty to transcribe a critical lab result not only in the EHR but in the paper charting. So, again either way you slice it there's going to be liability arguments that either the provider should have written in multiple sources or the physician should have looked in multiple sources. So, the concern would be by opening a stream of data aren't we creating a potential duty to review and act that clinicians may not understand that they're signing on for by accepting patient-generated health data. I think it's clear that if the addition of patient-generated data is not managed carefully it could give rise to liability just under this one prong and I know all of you are working on putting an infrastructure in place that would prevent that sort of situation.

And finally there's a lot of outside problems we can address with the questions but I would also just say there's an observation that with the multiplicity of data sources in a complicated HIT environment we're reaching the limits of the clinician's time, resources and cognitive ability to process this information in any meaningful way. So, I think I will end it there and I'd be happy to answer any additional questions.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, to all the panelist. Gayle unfortunately is on the way to the airport, but Gayle if you're listening I'll give you the first crack at a question because this was one that you had a prior interest. Are you there? Pardon me?

MacKenzie Robertson – Office of the National Coordinator

Paul, I don't see her on the line.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Oh, you don't see her? Okay. So, we'll give her a crack when she gets on line. So, questions. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I've been muttering this to myself all day so this seems like the right panel to say it out loud because it sort of feels like the right kind of legal word. So, provenance, we have information now coming from lots and lots of data sources and historically the electronic systems have assumed the information in the electronic record is generated by this community of users and we track the user and time stamps and all that kind of stuff, but, generally not sources because the source is inside our system. And it seems like we're hearing lots of examples today of all kinds of data coming from all kinds of other sources, it could be other EHRs, it could be individuals contributing, it could be technology, monitoring equipment contributing. So, sort of where are we on that? That whole notion of the record systems having an obligation to track where the data came from and any examples of people doing that well or doing it poorly?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

It's interesting enough that you mentioned this topic. I happen to work on the HL7 Committee that has to do with records an evidentiary management support which is working on this very precise issue about how do we embed the source of information that might be in a note. I was really shocked when I joined the group that that wasn't in place already because for me as a lawyer that's a fundamental that, you know, when we're talking about the authenticity of a record we can verify who made what notations when and it was surprising to me that you could have vitals taken and put into the progress note and it looks like whoever authored the note did everything that appeared there but that certainly wasn't the case.

Relating that the patient-generated data it's very concerning to me as the attorney who is speaking in the record. So, if this is a statement from the patient who has entered it in themselves which may or may not be accurate, which, you know, is not a clinician talking, I don't want it attributed it to my doctor that I am defending. And it makes my job a lot harder for dealing with an EHR that doesn't have the capability to track where the data sources are coming from. So, hopefully that's something we're moving towards.

Deven McGraw – Center for Democracy & Technology – Director

So, when I was preparing the testimony for today I got a lot out of…and there's not a lot detail in my testimony on this point because I'm not an expert on it, but I certainly took a look at materials from both HIMSS and AHIMA on legal medical records basics, right? And so any information that's going to be incorporated into an EHR there are just some basic functionalities that it should have and that includes an ability to know the source of the information and to have its integrity protected so you know that it hasn't been altered in any way.

And that's…and so have we made any progress on it. I suspect there's a whole body of work that's been done and unfortunately had I looked into this before I was reading my testimony I would have, as member of the committee, said well we really need to have somebody for HIMSS or AHIMA here. So as we continue to sort of work on this issue I think we need to get the folks around the table who deal with sort of documentation and legal medical record issues around us so that we do this right.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Leslie?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

I appreciate all of this, this is really tough stuff to deal with. And I had a question, because so much of the data that we collect today is patient-generated, except for the clinical observations and results from systems or clinician's observations we ask questions and the patients give us a verbal report back and we then scribe that information back into the record and claim that to be more accurate than the actual source of truth which is the patient answering the question. So, I'm struck by that idea of who is the source of truth and accuracy when unless it's coming from a device or an actual observation of a clinician it is the patient's generated data. And could you comment on why that's so difficult than when we make it electronic from where we've been taking an oral report?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Well, I mean I'm looking at this from a legal lens and to me what I want out of a note or a record is I want some type of legal product that can demonstrate, you know, what were the contemporaneous notes by the provider and some of those notes by the provider might contain statements from the patient that they were taking at the time but those sorts of notes have a different legal weight to me because they are the evidence of the care delivered, they're what we are trying to defend. But, you know, I hear what you're saying and why is there…but the difference is you're trying to make a permanent object that you can use later for medical and legal purposes whereas if you're getting direct observations from the plaintiff or sorry the patient, I'm slipping into it, you know, things are more fluid, things possibly can change too, you know, when you're having a conversation nothing is set in stone but the whole purpose of making a medical record is trying to document for somebody else down the line what definitively happened and what you can rely on.

Deven McGraw – Center for Democracy & Technology – Director

I think it's also the case that as we sort of think about the idea of having data coming directly from patients into an EHR versus the provider's interpretation and documentation of what they hear from the patient, it almost calls into question whether we are morphing the EHR into something that it has not historically…into a role that it has not historically played. It's a business record or historically, it is a business record that the provider keeps in order to satisfy the provider's legal obligations to provide care in accordance with evidence standards in order to be able to document care for payment purposes and to be able to justify decisions that were made if ever challenged. It hasn't historically arguably served as the source of truth. It has served as the providers of documentation of what they did for a range of purposes.

So, to the extent that we are a seeking a different healthcare system where more data from patients comes in I think we have to acknowledge that we're pushing against some rather old saws here about what the purpose of an electronic health record is. And ultimately we will have to come to a place where the health record continues to provide the important role that it has always provided for healthcare clinicians and the clinical team at being able to sort of document what they did but on the other hand providing a source of information that can be shared with others and potentially used for other purposes. We're in some rather new territory here and I think we have to, again because of the historic role that the EHR has played and what we may be envisioning it to play in the future may be a bit different but it's still going to need to also play its historical role. So, how do we do that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'm going to pick up on that comment, which I think is very germane. So, right now we're talking about patient-generated or patient supplied data. I think this generalizes and one of Chad's comments was the multiplicity of data sources really increases the liability and that's just a legal tenant I think. So to Deven's point instead of a single individual's record or documentation of history it has become…actually the problem is it's become more than the source of truth, it's the source of truth and non-truth. And that is what we've struggled with all of this morning.

So, in some sense is it really the, who knew what when? And that's what it's become or maybe you could describe your approach to how do we make this much more of an asset than a liability. What's the best way to handle this record which has become a repository of data from all sources and not knowing which part is truth and part is not truth. But is it only who knew what and when that is going to determine the liability or is there a different approach to just favor it and biases in terms of what's the beneficial impact to patients?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

I mean, I just think that for a clear record you need to have a way that can identify the source of the information whether that's on the face of the record itself but that might make for a kind of cluttered record or if you have another filter or layer where you can somehow look and see, okay we know…if push came to shove and there was a question about was this from the clinician or did it come from the patient that you could somehow through the backend figure that out definitively. That's really I think what's needed.

And, you know, it's funny I do like the concept of sources of truth but usually what I'm dealing with are sources of truth, right? You know, it's much more like the story of Rashomon where everybody has their version of the truth and that's really what the courts in my world are parsing out. So, you know, the patient thinks they communicated x-y and z, the clinician might only have gotten x and y, you know, so I don't think we're ever going to get to a perfected EHR record but I think we need to be able to document where the sources of information came from in an easy way.

Prashila Dullabh – NORC – University of Chicago – Program Area Director for Health IT

You know, I mean that's a big question and based on some of the work that we've been doing it seems that, you know, you sort of have to break it up almost into sort of manageable steps, right? So the ease of electronic health record, there's all kinds of data that, you know, people might produce that may have, you know, clinical import depending on the situation or not. But maybe one way to think about this is, you know, with, you know, everyone's collective thinking identify certain areas of the medical record that, you know, can get opened up where patients can start providing feedback and maybe initially that's looking at some content in the record and somebody providing feedback or it may be some, you know, other type of information that the patient may provide in advance of a medical visit or something like, but break it up into sort of manageable steps.

And then identify, you know, the use cases that would be most valuable, you know, given the current state of where we are. Identify the processing that needs to occur depending on, you know, how that information is being introduced, how that's going to be processed within the clinical context inpatient, outpatient. So, we sort of break it up into sort of, you know, more manageable fragments and then, you know, incrementally as you work out the kinks in the process, as well as, you know, some of the issues around the legal and liability considerations as well, you know, increase what you do. I mean, that, you know, that's what it seems like from what, you know, we've been looking at. Even just thinking of the Geisinger pilot where just the medication, I mean there's lots of information in MyGeisinger that patients can see but it's just the medication list that's getting prepopulated right now that the patients get this in advance of their, you know, appointments where they can provide feedback so just that aspect.

And then they have a whole process in place on how that information is received, adjudicated, reviewed, how the pharmacist, you know, information is…actions are recorded within the electronic health record so that they may, you know, sort of persist over time and in terms of the source of data be identified, you know, where did this information come from, what were the actions that resulted in a change so there's traceability.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I may not have been clear in the point I was trying to make, which is that I don't think is a patient-generated data problem, it is the fact that we're getting data from multiple sources and then the who, what, when, where and why starts coming in. And so, I'm thinking is there a way to deal with the broader question of when you have multiple sources and no single person may know all the things in your Breeden case and in one case they said well you should have been reading all the sources, wow, that's going to be hard for us. But even reading all the sources in one place could be a hard thing. So, can we look at the general problem and as I said bias it more towards the benefit then the liability. Is there an approach for that?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

This is appropriate, is there a way to distinguish communication that's, oh boy it's sort of materiality, right? What is material to care might be in the eyes of the presenter and back to your flag system, you know, I'm a patient I believe this is important to me and that you should know about it. The doctor might receive that and say that a bunch of noise. But it was important for the patient to convey that, perhaps it's not material to care but material to the confidence of the patient which then does, based upon Judy's testimony earlier really get to better outcomes for the patient. So, this is hard.

Deven McGraw – Center for Democracy & Technology – Director

Yeah, no it's hard, I mean, you know, we've also heard…it's interesting Paul that you framed it in terms of sort of the cacophony of data noise that we may be introducing through Meaningful Use inadvertently where people are suddenly having access to or having information downloads into the record that they didn't have before and being able to manage all of it is maybe a design problem as well like nobody wants data for data's sake, you want the information that's valuable to you at the point where you're making a decision. How do we ensure that that happens and that would include data that might come in from the patient where there's again, I think a perceived value on the part of the provider. It's pretty critical here because I don't think we're going to be able to force nor should we, anybody to accept a data stream that they have no intention of looking at or using, because that is just a recipe for a problem.

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

I think as this gets more and more complex in terms of the numbers of potential data sources that are coming in to a centralized place. I think we've got to develop technological tools is the bottom line that is able to mine the data and pullout pertinent critical things that could be missed in this massive data it's the only way I can think of but I'll defer to our technology experts.

Deven McGraw – Center for Democracy & Technology – Director

Here's another thought, today it might make more sense from a legal risk threshold to say don't give me any of this stuff, right? Because I can't manage the data flow, but as the standard of care evolves you may be getting yourself into trouble by saying, no don't give me any of that stuff because I don't have time to manage it, because ultimately, and Chad you can disagree with me if you think I'm not right about this, but from a…not a constructive stand-point, but what should you have done to treat this patient, maybe that you will need to start accepting some of this data in a manageable way because you're sort of siloing it may, ultimately as care patterns evolve, become a liability for you as well. So, I mean it's just going to shift over time.

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

I mean probably it's heading there but I think that, you know, clinicians are also put in a position where you don't want to have all this unreviewed data sitting around because you don't have the time and you don't have the cognitive resources to get to it in your busy day, that also looks bad from a liability point of view. You have an aggressive plaintiff's attorney who does new discovery and figures out, oh, hey you didn't review all of your patient data for 3000 patients, you know, in some ways it's probably safer not to accept the data stream until you can set up an infrastructure to manage it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay we have a lot of healthy discussion. Eva?

Eva Powell – National Partnership for Women & Families

I'll give a caveat to my comment that I don't…I have empathy for physicians in this world today, so this is not meant as an implication that all of them are out to do nefarious things at all. But, I just am reflecting on Nikolai's testimony earlier today and thinking about his…what he termed I think the verbal agreement and had his situation turned out differently and he would have died as his friend his did there would absolutely have been culpability there because there was information provided verbally that was ignored for some understandable reasons, but the bottom line is that the patient suffered. And really the bottom line of what we're talking about now is moving that verbal agreement into a form that can be shared and provide the information where it's needed.

And so in some ways even though in that situation had his situation turned out differently there would've been culpability, there would have been no legal liability because there was never any documentation that this is what he had said and so in my view part of what we're talking about is protecting patients. And not necessarily protecting doctors, which is your job, but ultimately the two come together at some point. And I'm wondering and some of this is rambling but I don't want us to lose sight of that, that you cannot prove a negative and so from a legal stand-point information that is already being shared but for whatever reason is not being acted upon for some very human factors puts the patients on the losing end, sometimes losing their lives.

And what we're talking about today is instituting something that may help that but there are some real barriers here that in essence are trying to protect physicians from any sort of culpability. And this is not a good place for us to be. I mean, we're here. We have to deal with these issues but I'm wondering if…just an observation. All of this is under a bigger umbrella of accountability and the legal liability system is one branch of that but the quality measurement arena is another branch of that and while I don't think either is going to replace the other or neither is going away. Is there a way to advance the quality measurement arm of this which clearly needs a lot of work as well in such a way that provides a more effective means of holding providers accountable in a way that perhaps is fair and more accommodating of human factors?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Well, I think maybe to address it, I just a have a short anecdote. When I was doing a presentation a doctor came up to me anonymously in the audience afterwards and said I had this situation where a patient came to me with a flash drive, it had a PHR, all these external documents, hundreds and hundreds of pages, and the patient asked me to take it and I wouldn't because I honestly didn't know what I could meaningfully do with it for one and I didn't know what he was expecting me to do with it, and I didn't know what my legal obligations were. And to me having heard the testimony this morning from Nikolai I feel like doctors feel like they're in a situation right now where there is a missed opportunity because there isn't a framework really to deal with the patient-generated data in an effective way.

So, I don't think, just to bounce off the first part of your comment, you know, I don't think wholly concerned about their own liability but they also just don't know, you know, they might not have the infrastructure to deal with some of the issues. But, and then the second part dealing with the data, you know, I think that, I mean that might be a way to proceed rather than…I'm floundering a little bit here. I guess basically that's a good idea to keep a hook on the clinical benchmarks and kind of sell it that way and I think build up in, you know, ways to use the data to basically educate the physicians about what they can do with different types of patient-generated data.

Eva Powell – National Partnership for Women & Familiesfor Women & Families

Right, well and I've seen, I think there's at least one paper out there and back in my QIO days I've heard it said that ultimately failure to meet the basic quality measurement criteria could feed into the liability world somehow, that if you…because so many of them are based on standards of care which is part of what I think we're trying to work on in the quality measurement arena is to make them a little higher bar, but they…to me there seems to be a lot of interplay there and it's all about accountability and how to do that in a way that's meaningful and fair to all parties. And, so, yeah, thanks.

Prashila Dullabh – NORC – University of Chicago – Program Area Director for Health IT

I think also, just sort of following up on the point there a little. I mean, it would seem that, you know, your point, right? I don't think providers, you know, don't want to deliver good care, I mean, that's not, you know, the basis of how anyone, you know, any one of us would operate, right? Do no harm is what we learn first. So, you need to, you know, in some ways sort of create an environment and I think some of this is beginning to happen as, you know, EHRs are becoming not just, you know, what they've been used to record the clinical encounter but more a way where a patient and a provider can use that as a mechanism to dialogue. I mean, that's what we're seeing, right?

When a patient sees part of their medical record and they say I see this but I don't understand this, and what about this, you know, it's sort of creating an infrastructure for dialogue which, you know, in some ways is cementing a cross relationship. So, like I think, you know, collectively, again in terms of thinking about the problem, you know, understanding what providers, you know, need from the perspective of how they deliver care.

I mean, again going back to our research in this Geisinger context when we spoke to some of the providers, you know, what they reported was they had limited time in seeing their patients, so the fact that a patient took the time to actually review the record, update their records, send information, made their medication reconciliation efforts that much easier, which saved them even more time in the clinical visit. So, like, you know, thinking about what were those…what aspects of this that can actually drive efficiencies from the provider side but also how they can be then, you know, delivering better care to their patients, making important considerations.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

Yes, I just wanted to go back to one of the comments that Dan Campion made and also the comments around looking at what was done in other arenas because I know in looking at EHRs and all we looked at AHIMA and HL7, but we through CDISC have been working with HL7 for the past 10 years and I think this is where some of the clinical research experience could be a wealth of information because all of the data was in paper case report forms until about 10 years ago and when they started trying to collect that research data electronically there are regulations around how that data are collected that require an audit trail. So, all of these standards and the technologies developed for research carry and audit trail and the 21 CRF 11 regulations are basically the research HIPAA, and it shows where the source is, what the data were, what time they were collected, when, who was logged in when they were collected, and if a change was made who made that change and why. So, there's a complete audit trail and the standards that have been developed in XML carry that information. So, when Dan talked about the RFD I'm not sure it resonated enough that everybody understands what that involves, because that includes pulling a form from a remote source into an EHR instance and then pulling data out and sending it with an audit trail to the requester of that information.

So, I think there's a fair bit of information that could be brought into play in this and just borrowed from that industry because they've been looking at patient-reported data for a long time. They noticed that when a patient was taking medications on a trial that when you try to put things in a paper diary people put that together in the parking lot before they go into the doctor. And by giving them an automated device they could track when that patient entered that information about when they took the pill or whatever and they can track it and they get much more accurate information using devices like that. And that data can then come in through an audit trail source.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, do you have any comments? Tripp?

Tripp Bradd – Skyline Family Practice, VA

In Eva's word, I'm a non-nefarious physician and I honor non-nefarious lawyers. You know, I think what Deven said about a culture change and how it's running right against everything else we're trying to get done here is interesting. You said where there's a will there's a way as long as it's legal of course. You know, I live in the world of kill words, one of those kill words is HIPAA another one is stark or let's ask legal, you know, and then all of a sudden like roaches when you turn on a light in the kitchen everyone skitters away from the conversation. But the fact of the matter is, you know, one of the problems I've had…and we've moved from adoption, you know, as a physician and trying to encourage other physicians to use EHRs, now to access for patients.

As Chad mentioned there's a lot of problem with stuff to manage and for our patients it's the firewalls that have been created for them to hammer through to get to the portals. We spend an incredible amount of time dealing with patients learning how to get their passwords and all their other authentications, I guess we'll have to go to retinal scans I don't know, anyway, you know, the trouble is they…one of the reasons what I wanted to ask about was there are a lot of tensions between HIPAA and all the things that people perceive including the vendors. And how we can from a policy perspective make it easier for the vendors to help give our patients access to us and from us to them?

One other question was we live in the World Wide Web. Have you all or are aware of any offshore problems, I mean we always think in America we're very egocentric, but now we're in the World Wide Web and a lot of healthcare IT is being pushed out beyond our shores and I'd like to hear comments on that too if…you know, in terms of how you again, with patient-generated data, how you might perceive that?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Well, I'll talk about the first part I guess because we run into this a lot, you know, I think one of the components of the HIPAA security rule that is so problematic is the encryption requirement when it comes to electronic communications typically because, not so much because of healthcare institutions because, you know, you have IT departments, you can get that right. The issue is the patients who are consumers who want to use their smart phones, who want to use their Gmail accounts, who want convenience and don't necessarily appreciate the, you know, why something like the security rule about unencrypted transmissions was put into place.

You know, and I think if you're a rural doctor who has a patient population that really wants to use this type of technology there's a great impetus to try to end around it and in fact the AMA put out guidelines that, you know, allow you to do an informed consent and authorization just to do that because I think there was such a demand to get away from, you know, look our patients aren't worried about their, you know, request for a refill of a prescription getting hacked by teenager in Russia. They're just not concerned about that. They just want the ease and convenience of it being in e-mail, you know, and so in that regard when talking about patient-generated data we're talking about mostly patients using smartphones and cell phones and so you're going to have questions about like, well is the App as it's created, does it comply with the security rule when I transmit this to my physician, am I committing a data breach or is the physician inducing me to commit a data breach by asking me to send this material over an unencrypted channel?

I think that aspect of the security rule is the most problematic in terms of trying to craft policies to facilitate sort of that ease of flow of communication between doctors and patients, you know, I understand there are counter arguments to it, but I can certainly empathize with those practitioners like the ones at the AMA who came up with this end around because it's so troublesome.

Deven McGraw – Center for Democracy & Technology – Director

It's so interesting, that we're talking about encryption being perceived as a requirement when in fact a lot of healthcare providers don't actually encrypt data for…you know witness the wall of shame and you'll take a look at a lot of healthcare providers who mostly for data at rest, not necessarily in transit. Having said that clearly we have an enormous need for more specific guidance I think from the regulators about what is and isn't permitted when you're talking about communications with patients. And whether it is okay for example if the patient says just send me this to my work e-mail and even if you've said are you sure, you know, this is sensitive health data going to an employer based e-mail are you sure that's what you want and they say okay, that in fact it's okay for the provider to do that.

And I have heard anecdotal comments from staff at the Office for Civil Rights where persons have said, yes if you're patient wants their data in an unsafe format as long as you make a safe format available to them and they say no it's more convenient for me to get it in this other way, then it's okay for you to do that because it's ultimately about giving them the access to their data that they have a right to do so. But I haven't seen that written down anywhere and it sure would be helpful if it were.

Nobody wants to be a test case, not with the liability penalties having been increased so much. So, you know, the Office for Civil Rights has actually put out calls for…saying tell us what you need more guidance on because we'd like to give it to you. I mean, certainly recent discussions that I've attended in public forums that has been mentioned. I think if we come up with a list and say specifically what we think would be helpful such as clarifying where the liability rests for example when the patient says I want you to send this to me by e-mail to my work and there is a breach that happens in the middle…just those little things like lack of clarity is a killer to the type of innovation that we're trying to achieve here.

On your offshore point, it's really still the providers responsibility to adhere to HIPAA and to the extent that they're using an offshore provider as a vendor for their electronic medical record it doesn't matter that the vendor is offshore from a sort of legal reach of the law stand-point because the reach of the law is for the provider and so they have to make choices in that regard.

Tripp Bradd – Skyline Family Practice, VA

I meant the patient, if it were the patient.

Deven McGraw – Center for Democracy & Technology – Director

Oh, the patient. Again, once the data is in the patient's hands HIPAA doesn't apply even if they got the data source from a provider and there unfortunately, you know, the legal landscape is buyer beware.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

MacKenzie, is that Gayle by any chance?

MacKenzie Robertson – Office of the National Coordinator

No, it's not Gayle, its Kate Christensen who is calling in for Jamie Ferguson.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so we'll take it in turn then. We only have 3 minutes. So, Amy?

Amy Zimmerman – Rhode Island Department of Health & Human Services

I'll be quick. My question was related to something that we heard in the testimony earlier and some experience we've had in Rhode Island and I'm going to make a quick analogy. We've been discussing the integration of behavioral health into our HIE under a SAMHSA Grant and one of the issues that has come up and it's got an analogy here around too much data, what data do I want for my ability, is when we had a discussion with our providers about getting data out of the HIE that, you know, we had the right consents for it to go in under CFR 42 but on coming out they're very concerned about putting it in their record and then responsibility on redisclosure.

And the analogy there was when we were, you know, having some discussions about how we could do this it was like, well if I could choose to go get that data or not choose to go get it and put it into my record, you know, would that be okay, then I know at least if it's tagged then I have some data that I know I can't redisclose.

My point is what happens…the question is and it was I believe our testimony this morning from Partners when Neil said physicians can choose to accept the patient-generated data or not and I think you were addressing this before, from a legal liability stand-point if physicians have access to data choose not to take it or choose to take it…and I don't know, under Deven under your projects whether physicians had choices or not or how they felt about it. I know we had some physicians in our community that are just very fearful of anything that doesn't…they don't want it because then it's going to create too much trouble and, you know.

So, what happens under that sort of I choose to download it or I choose to accept it or it's sitting there and I don't want to accept it because I don't have the time to deal with it, don't want to deal with it, I'm afraid about redisclosure, whatever the case may be. How does that play in here?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Well, so I mean basically it can cut against you either way. So, you know, if you accept it then you're responsible for it. And if you decline it then you're going to hear ladies and gentlemen of the jury, Dr. Smith could have known about this but declined to even look, you know, I mean seriously, that's how it plays out. And it's even worse if you have a backlog queue of patient data that you haven't looked through.

Amy Zimmerman – Rhode Island Department of Health & Human Services

Yeah, I didn't look this morning, I was curious how…what happened in the Partners case where they didn't choose to accept the patient data, because I think he clearly said they needed to choose to accept it.

Deven McGraw – Center for Democracy & Technology – Director

In none of the Project Health Design projects was data covered under the Part II Regulations involved. So, there was nothing that would have had a redisclosure prohibition attached to it. Having said that, there was behavioral health data that wasn't substance abuse treatment related that was involved in a least one of the projects and it also involved minors in that project. And essentially, you know, who we're sort of talking about they're moods in certain circumstances in their life, which is, you know, sort of relevant to their ability to try to manage some of the more depressed and managing their…they were overweight or obese some of them and the idea was to start gauging sort of when there were triggers for them not to follow their exercise plans or their nutrition plans and see if you could get that to change by having them collect that data routinely. But the way that the youths collected it in the project and the health coach monitored it and there were decisions made about when there were clinically relevant indicators that would then need to be sort of tee'd up to clinician or physician level examinations.

So, there was a decision made by everyone participating in the project that yes, we would collect that data that somebody would be monitoring it on a routine basis with the teams but that only some of it would in fact be entered into clinical workflow and only in discrete circumstances where it needed to. So, I'm not sure how that stands up from a malpractice liability stand-point but it definitely got the grantees comfortable and they wanted to move forward with it because they believed in the value of the project.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Jodi, did you have anything?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

I did, but I didn't want to have you delayed…ask a question or not.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Pardon me?

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

I just asked if you want to stay on time?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, so Kate on the phone?

Kate Christensen, MD – Kaiser Permanente

Oh, thank you. I just have a quick comment. I'm Kate Christensen and I'm an Internist with Kaiser Permanente and the Medical Director for our patient portal and also a hospice doctor. So, with all of those hats on I just want to say it's not just a liability issue for physicians and I know you've heard this but it's really a work day issue, what we do with our time, and I was really struck by a comment on a previous panel about the Twitter-ization of healthcare and the increasing expectations about what is proper to be shared in terms of our personal information and I can see that once sharing health information and health data goes mobile that the expectations for physicians for managing this data will be huge. So, we just need to really take account of the need to restructure what the doctor's work day looks like if we're really going to expect them to manage all of this data. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, so Jodi since we're an advisory to you I think you can ask a question.

Jodi Daniel, J.D., M.P.H. – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

This is Jodi Daniel, I just wanted to ask, we talked this morning and I think George actually said it well when was trying to come up with a taxonomy of the different kinds of patient-generated data that we're talking about. From your perspective of sort of the risks of incorporating patient-generated data into the clinical discussions and into EHR are there some areas where you think there might be some low hanging fruit and where the liability risks are minimal versus those that maybe of greater risk because they're more, you know, they're less chartered waters or something like that. What's your sense of the relative risks of different kinds of information?

Chad P. Brouillard, Esq. - Foster & Eldridge, LLP – Healthcare Attorney

Well, I think generally if you're talking about fixed data, you know, like someone is uploading their blood sugars and things like that, I mean that seems to me to be kind of a no-brainer in terms of high efficiency, very low liability, you know, I think the more you get into free flow of patient narrative that's where it gets much more dangerous because then you absolutely have to have a pair of eyes going through the thing in-depth to make sure there's nothing concerning that needs to be bumped up.

Deven McGraw – Center for Democracy & Technology – Director

I wouldn't disagree with that at all and again, you know, so Patti's up to testify more about what happened in Project Health Design, but that data was more along the lines of potentially riskier data, not all of it, but a good portion of it and in none of them was there sort of automatic data feed into the EHR in none of them. It was all very carefully managed and planned with the clinicians.

Prashila Dullabh – NORC – University of Chicago – Program Area Director for Health IT

You know, based on some of the work that we were doing under this study it seemed both on the literature as well as, you know, various discussions with entities that had exposed various aspects of the medical record, so we saw areas that people, you know, thought it would be good to let patients, you know, give us comments and feedback so we can enhance what we know about them, and so we can take better care of them, they were around allergies, medications and immunizations. So, you know, there seemed to be some consensus that, you know, when records are made available, those areas might bring value if patients can give feedback on that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, thank you and thanks to the panel for a very informative discussion. Okay, our final panel today is aptly named challenges so it's wide open. And since we've actually heard a couple of times from Project Health Design, one Nikolai was participating in that project and Deven just reported on some of the policy issues, we're going to hear from Patti on this final one to share with us some of the result they have, it's all patient-generated data. And David Lansky is going to help moderate this panel.

David Lansky – Pacific Business Group on Health – President & CEO

Thank you, Paul. McKenzie, do we have Lacey on the phone?

MacKenzie Robertson – Office of the National Coordinator

We do.

David Lansky – Pacific Business Group on Health – President & CEO

Great. Well, thank you all for coming and helping us wrap this up; we look forward to hearing your testimony. As you know the bios are available in the packet and I think we'll start with Patti.

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

Thank you very much. I want to thank the committee for the opportunity to address this group. I'm Patti Brennan, I'm the Director of the National Program Office of Project Health Design, this is a Robert Wood Johnson funded initiative it's been operational about 8 years. We've engaged 14 teams around the country to think and rethink personal health records, learned a lot about what people pay attention to in everyday living which we call observations in daily living and learned a lot recently about how clinicians interact with this data.

As I begin I want to thank also all of the clinicians, the designers, the IT teams that we worked with and most importantly the over 200 patients we've involved in these studies who've given us the experience to be able to come to you and share some of our insights.

In today's work I want to say first of all we very much support the Workgroup in attending to patient-generated data in the Meaningful Use criteria, particularly for Stage 3. We believe that supporting patients and clinicians as they work, the criteria that support the integration of patient-generated data into the clinical care process and into the clinical care record is essential and we believe that this partnership will both enhance the delivery of healthcare in the United States as well as stimulate the technology industry for there are many technological problems to be addressed.

Our group wants to make three key points drawn from the experiences of the current five Project Health Design teams and if you look in the handout materials, the last section is the Project Health Design reports and you'll see our architectural drawings as well as some of the summary of the data I'll be presenting.

First and foremost is we need to expand the idea of patient-generated data beyond the idea of data that patient's generate that is acquire, develop and send to someone else to data that patients also define, things that the person views as important whether it's the…or the family dinner conversation or how well I slept last night, or whether or not I'm able to pick up my daughter. Second, we need to recognize fully that sharing patient defined data with clinicians improves the business of healthcare and third we assert, it has already been asserted today, that existing technologies are adequate but not optimal for the clinical integration of patient defined and patient-generated data.

We expanded the concept of patient-generated data to include a wide range of exemplars. In a group from the University of California at Irvine studying mothers who cared for very low birth weight babies who were at high risk we learned that having a fussy meter mattered a whole lot so that moms could keep track of what was going on with that baby during the day. We learned taking pictures of baby poop is actually important because sometimes what a mother thinks is greenish-brown is really brownish-green. But importantly we learned that by engaging people in the care of the patient, the little tiny baby at home through the technology we were able to understand the experience of care in everyday living and that's critical.

Secondly, we learned that providing and sharing this data with clinicians really did change the business of healthcare. At the University of Virginia the RTI research team found that by having patients who had asthma were at risk for depression, by having them track their moods, by having them track when they're using their rescue inhalers, and getting that information to a group of triage nurses who escalated it to the clinician as appropriate lead to several clinical care changes. Two patients had the wrong diagnosis they were being treated for asthma when what they really had was COPD and more importantly there was one patient who confused her asthma rescue inhaler with her asthma maintenance inhaler. So, finding that out and being able to intervene in the points between care is an essential part of why tracking patient-generated data is critical.

We learned, as Nikolai explained to you earlier today, that the technologies we have right now really aren't very good to copy manually data from a computer screen onto an iPad and hand the iPad back to the clinician who has to then again transcribe from the iPad back into the computer screen makes no sense. The opportunity of introducing errors all the time is very challenging. Our clinicians in the InTouch Team who you heard about with Deven's remarks a few minutes ago had to take a PDF from the patient that could be accepted into the clinical record, it could be scanned and put in as long as the clinician matched that 17 digit patient record number accurately and without error and did that taking precious time away from patient care. The technology should support the patient engagement not simply facilitate the records management.

The panel asked us to address several questions. How do we make this cost-effective and sustainable, and how do we assess the cost and feasibility, and return on investments. We were also asked to address standards. We believe, as others have advanced, that there is an important role for data standards, language standards and terminology standards but we don't want them to interfere with innovation. It may be more important to share the information rather than standardize the data.

And finally the business models. We need to think about two kinds of business; the healthcare business and we've heard a lot about the fact that under accountable care models the business of managing self in the home may be very important. We need to think about other health care models that could be enhanced by that, but we need to look at three different industries, the consumer electronics industries, the Health IT industry and the device development industry. Thank you very much.

David Lansky – Pacific Business Group on Health – President & CEO

Great, thank you.

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

I didn't want David to tell me to be quiet.

David Lansky – Pacific Business Group on Health – President & CEO

Perfect pacing, thank you. Gary?

Gary Capistrant - Public Policy for American Telemedicine Association – Senior Director

Hi, I'm Gary Capistrant, Senior Director of Public Policy for American Telemedicine Association, I'm also speaking on behalf of Continua Health Alliance. Telemedicine is about the delivery of health services via telecommunications such as video conferencing and remote patient monitoring. There are a variety of other terms used eCare, mHeath, remote care, telehealth that deal with this area. ATA is an umbrella organization for telemedicine. Continua is focused on the remote monitoring of people with major and often multiple chronic conditions in the interchange of the devices and the data. Most Continua members are also ATA members. Since you've already heard and read a lot about patient-generated health data I'll try and make our points very pointed and brief.

What should your committees do, ONC, HHS and the administration do in the short-term? RTIs paper prescribes a briar patch of issues; most important is that progress be made now with what is doable and priorities set for increasingly difficult actions. You have a good start on acute care encounters in hospitals, and doctors offices, now the need is to develop a progressive agenda for EHR and HIE to address the critical issues of chronic diseases such as preventable costs, uncoordinated care, lacking longitudinal data and infrequent patient engagement. This is key to enabling independent living and aging in place.

The standards for Meaningful Use incentive payments drive the software functionality available in the commercial market place. Thus, the next step should be a Stage 2 stronger than proposed about retaining already digital patient biometric data in helping patients with day-to-day management of their conditions. We suggest starting with RTIs figure 4, the asthma scenario, a very easily to deal with machine to machine data arrangement.

ATA and Continua provided specific input on our Meaningful Use comments letters and some of the ONC beacon communities, and I guess we're going to hear some more soon, are already models for integrating the chronic care and patient data.

In the chronic care the federal hand is very visible, although neither very steady nor strong. It was interesting that the written testimony from CMS does not even mention chronic care. The federal role as chronic care payer is huge, particularly with the VA, Medicaid and Medicare. With the Affordable Care Act, there is a spurt of service models such as the Medicare Independence at Home Demonstration, Medicaid Health Homes, bundled Medicare payments and the Center for Medicare and Medicaid innovation. There are needs and opportunities for the payment and Standards Committee, and ONC leaders to lead the specification of required data elements for the payment of chronic services right now.

In later months ONC should be the national coordinator in two priority areas, specify other data in standards needed for better chronic care such as patient outcomes and patient satisfaction. Number two is foster useful tools for people with prevalent chronic conditions and major illnesses, and their multiple caregivers, especially using easier, better, emerging mobile consumer devices.

Before Meaningful Use Stage 3 and for Stage 3 we need to be much further along with patient data and tools for chronic care. We need a steadier and stronger federal hand. It is important for individual's health and critical for long-term improvements in patient chronic care, excuse me population chronic care. ATA and Continua can and want to be technical in implementation resources for you. Thank you.

David Lansky – Pacific Business Group on Health – President & CEO

Thanks, Gary. And you liberated 30 seconds for us, thanks. Lacey, are you available on the phone?

Lacey Hart, MBA, PMP – SE – Program Director – Minnesota Beacon

Yes I am, thank you.

David Lansky – Pacific Business Group on Health – President & CEO

Great, thanks.

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

Lacey Hart, thank you I'm speaking to you today as a representative of the Southeast Minnesota Beacon Community only and not as a Mayo Clinic Employee. I'm also going to limit my comments to what we've collected of patient-reported outcomes and quality of life measures. As we defined our Beacon Community delivery system to be patient centered we found significant value in using patient-reported outcomes and quality of life measures, particularly for those patients with chronic conditions such as diabetes.

Patients know when they're unwell often in the absence of positive laboratory tests or clinician identification of a problem. For example patients noticed buzzing in their hands and feet 2-3 months before a diagnosis of peripheral neuropathy. Cancer patients who indicate a quality of life deficit have been associated with the doubling of the risk of death. Yet our cultural perceptions prevail in the clinical setting that patient-reported outcomes are less than reliable, lack standardization, are difficult to collect or when collected too burdensome to manage.

Our challenge within our Beacon Community was to illustrate clinical utility of patient-reported outcomes and quality of life as well as find a common sense approach to collecting these measures, sharing the measures and integrating into our care delivery workflows with a common decision support response system.

In our work patient-reported outcomes have been seen to be just as accurate and reliable as laboratory tests for detecting clinically meaningful deficits and well being. Indeed patient's self perception is superior to machine indicators because it includes the interpretation and information from the computational capabilities of the human mind. We see this in other clinically excepted measures. For example a blood pressure rating in and of itself is misleading but when based on the individual norms of the patient can be clinically actionable.

We notice applying the same standardization and processes used to develop these lab-based assessments with simple single indicator scales quality of life scores can let us know as to whether or not something is normal for that patient or whether it indicates the need for a clinical investigation intervention. In comparison similar indications for single item measures of fatigue and pain have had the same clinical utility and decision support workflows.

In our experience for patient-reported outcomes to be affected and acted upon as clinical vital signs like blood pressure they need to be routinely and efficiently collected, interpreted, and acted upon consistently without overburdening the clinical care process. This rules out the possibility of using many research trial based patient-reported outcome measures or the typical approach of compiling a comprehensive system review of all aspects of patient well-being, involve the prohibitively large number of assessment items that's just simply too long and burdensome to be of practical use in the clinical setting.

We have found that psychometric integrity is actually less important than the clinical utility. In our community we limited the focus the well-being process on the goal of identifying the greatest concern that that patient had on their mind at that particular time. These options were actually defined by our patients.

We ask only a small number of generated QL and diabetes related items to assess their chronic condition management and the impact on their quality of life for their chronic condition. In total less than 10 items are asked of the patient in a consistent way. They were assigned a 10 point scale. We've achieved with these test questions on a scale of 0-10 that we can clinically leverage patient-reported outcomes to determine the patient's single most important concern, when there is a clinical investigation or intervention needed where there may not have otherwise been a flag in their clinical measures alone, and what are the clinical actions that can be taken to address those concerns.

By focusing on what is practically achievable being a minimalistic approach we can improve patient care because we deal with the most important concern for the patients. In addition with a minimalistic approach and a lab value association we can integrate into the clinical record and clinical workflow. However, in scaling nationally the challenge remains on the balance of clinical utility with a lengthy research driven focus on the collection of patient assessments. Thank you.

David Lansky – Pacific Business Group on Health – President & CEO

Great, thank you very much, Lacey. Let me…while we're all contemplating our questions let me pose one I think comes out of all of your testimony which is about standards and I heard a range of opinions about standards from the three of you, depending a little bit on the type of focus you've had in your work, and I know Continua has done a lot of work on standards for interoperability for remote devices, sort of a "objective" data, instrument often source data. Patti, you were offering some cautiousness about adopting standards as potentially limiting to innovation and I think Lacey in your last comment, you also said asking the patient what's their priority and capturing that data, you didn't speak specifically to whether that lends itself to standards and codification in the EHR, but I would be interested, again as you are advising us, how important is it that we take on standards promulgation and encourage the EHRs to capture standardized data to address these various types of patient source data?

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

I'll go first if I may, Patti Brennan, the most important standard activity that can be done right now is authentication and authorization, ensuring that the patient who is reporting or the person for whom the information is provided is in fact that person and can be well integrated into their information. This is a non-standard, non-simple strategy and it's critical so that we can link a clinical observation with a home observation.

My caution about standards actually addresses something that Paul is probably going to be surprised to hear me know a little bit about which is that you can separate data standards from language standards. Data standards and messaging standards these are very, very important and our example from the first round of Project Health Design in which Sujansky & Associates assisted us in creating a common platform, gives a model to show how a standard structure of data can provide a trustable and interpretable mechanism of moving data around and it allows for a variety of language implementations.

We recognize the data from the home may come in many formats, it might be in sound, it might be in pictures, it might be in words, and those words mean things uniquely to the individual so from the perspective of Project Health Design the importance is having a safe and secure transmission of information that is the personal story of the individual involved and it does compromise the ability to generalize across a number of institutions. It may in fact even interfere with a broad scale research report, but I would caution you not to over standardized language, which might obscure the patient's individual experience for the sacrificial strategy of research. Thank you.

Gary Capistrant - Public Policy for American Telemedicine Association – Senior Director

I'd say that the standards piece is very important and obviously one approach can be taken kind of from a financial stand-point, you know, what is appropriate for Meaningful Use payments, what is necessary for VA and CMS in particular to know about the services that they're buying and being a prudent buyer of those services. And, so I think that there is a natural tendency then to think in terms of, you know, what is appropriate information. CMS continues to look at, you know, more and finer measures of that and that's very important in this area of chronic care, remote monitoring that is a relatively new area and one that is much more amenable to some of the emerging technologies both to make the collection easier, you know, from the patient's stand-point but also from the physician's stand-point.

We do get, with the variations that are coming in with multiple innovations; I think there's also a need to kind of set small case standards about what some of those measures should be. So, that both applicants know what's going to be expected of them, but even more importantly, those that get awarded or participate in these programs that there is a collection of data and development of tools that go beyond the immediate need and create a basis of knowledge for what's going to happen in five years.

David Lansky – Pacific Business Group on Health – President & CEO

Lacey, do you have a comment?

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

Yeah, so we do believe in standards, particularly when you're collecting the data and we do exchange this information through our community. So, we had to have a consistent way of exchanging the information but the only caution that I have is that when you're collecting this information it really gets to the clinical utility versus perhaps the research or the robustness of the questions that you're asking. We really can take and boil down all of our questions and our scales to understand are we taking action or are we not? And it gets to the very basic premise of when you walk into the physician's office and they ask how you are doing today, that's no different, it's an assigning of value to that answer and then knowing whether or not you have to take action or not. And that's the level of standardization that we would require.

David Lansky – Pacific Business Group on Health – President & CEO

Okay, thanks. Let me see if people around the table have comments or questions? Art?

Arthur Davidson – Denver Public Health Department

Yeah, just, Lacey, this is Art Davidson and I just wanted to understand a little more about your last comment. So, I could understand that Mayo Clinic is quite familiar with standards and analyzing work process, and using the data that might come from the patient, but I just wonder, in your Beacon Community are there other providers than Mayo Clinic providers and how did that work with getting the data to them and how were they welcoming the data that the patient's provide in changing work process and workflow in their environment or using, as you said, to change some of the clinical activity?

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

Yes, and part of it was changing the perceptions of the usability of patient-reported information. When we look at it from a community perspective in changing how we deliver health care, providing care around that patient included more than just the healthcare providers, it included local public health; in our case it also included school systems for children. When you start exchanging information you're really trying to understand is there something clinically significant with the patient that you need to understand in between visits, so that was really the structure. At that point we not only had to collect that information but we had to share it.

And so how we do it, we have a tool and it can be administered at any point in time and it varies. We're doing research on when is it appropriate to administer the tool with different disease states and individuals of where they are in the severity of their disease state. But the tool just simply does ask what is their single biggest concern at that time because we can address those issues. But it also measures just their quality of life on a scale of 0-10 and we know from 0 being the worst it can be and 10 being the best it can be whether they're in that clinician's office or not, or their in their home if they're scoring 5 or less that means something is clinically relevant. We need to understand why their quality of life is not where we would expect it to be. And that sometimes maybe an intervention from public health or it may be an intervention from the clinician. So, you approach it very differently when you are looking at it from a community care perspective than in a single clinician's office.

David Lansky – Pacific Business Group on Health – President & CEO

Patti?

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

I'd like to comment on that also. Patti Brennan. And echoing what John Amschler had mentioned this morning, sometimes the reason we capture patient-generated data is to give it back to the patient and so understanding ways to make that data useful and interesting, and informative in the everyday life of an individual in part requires that we be able to represent it to them so they develop insight and can operate or act on information and believe that doesn't negate the need for standards for communication but it does broaden the usefulness of the data and maybe calls for a number of different kinds of standard framing or standard presentations of the data.

David Lansky – Pacific Business Group on Health – President & CEO

Let me ask one other question while people are thinking. Back to you, Gary, we talked quite a bit today about the volume of data that is gradually going to become available and obviously in the Continua Partner's there's a lot of volume coming through. What can you tell us sort of the state of the art of filtering that stream of data into EHR for clinical use and is this a problem that is sort of solved or it is one that we have to be especially attentive to?

Gary Capistrant - Public Policy for American Telemedicine Association – Senior Director

It's one that I think that is largely solved; it's an adaptive process obviously. Those that get the data tend to be where managing chronic care patients is a major part of their activity whether it's a medical home, special needs plans under Medicare or something like that where they do this routinely. It's very different when it's a single practitioner that has an occasional patient. So, essentially there are two ways of dealing with the inflow, one is that it goes into the provider's office and then there are software filters and whatnot that identify what's important and what's just normal trending information.

The other is emergence of some third-parties that are specifically geared to deal with the chronic care needs whether it's congestive heart, diabetes and so, you know, it's nurse practitioners and other kinds of folks that may see that for a variety of providers and will have their protocols between then and the individual practitioner as to what to be notified of, how to deal with it.

It's certainly an ongoing issue, you know, just as we all struggle with our e-mails and come up with different techniques for dealing with it, so, you know, it will continue to be an issue, but I think it's quite a fixable one and certainly better than not having the data flow.

David Lansky – Pacific Business Group on Health – President & CEO

I see someone on the phone had a question, MacKenzie?

Jim Hansen – Dossia

Yes, this is Jim Hansen on the Consumer Engagement Power Team. This is for Patti. Patti, given all the Project Health Design initiatives you've done, can you talk a little bit about the relationships between the patient-generated data and activation of them?

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

I can give an example and this is documented in the materials that we presented for the testimony. There was a group of young people, high school aged recruited through a school clinic in South San Francisco by Kathy Kim and the InTouch Group. They used an iPad Touch to allow the teams to track information about their mood, their desires for food, their food eating habits as well as to be able to send messages to their clinicians. They used the carrot platform as a way to aggregate that information and then created a PDF that was given to a health coach who could review with the team on a biweekly or bimonthly basis the things that were happening with the young person.

Some of our teens were able to use this as a way to remind themselves about themselves, to become aware of different aspects of themselves. Several of the teens that participated in this study lost weight over the six-month period of time, one lost as much as 20 pounds. The teens also were able to become much more aware of the triggers from their habits of eating. So, in terms of specifically activation this team actually did measure the patient activation scores for these teens and they'll be reporting it in their papers, but their behavior suggested their engagement with self and then their ability to interact with their health coaches was much improved.

Jim Hansen – Dossia

Thank you.

David Lansky – Pacific Business Group on Health – President & CEO

Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, there are a thousand questions but let me just focus on one that struck me in some of the conversation here, which is, I'm hearing that there's actually a different mix of people who might respond and that we've talked somewhat over the months about sort of the care team, and who makes up the care team, and the mix of professionals, and nonprofessionals that are involved, and I guess I'm hearing that in this whole question of how do you deal with the flood of information, that it also raises who should respond, and you're talking about health coach as part of this process, but I'm also hearing it could be a much broader set of people who are kind of plugged in and can respond, and now we short of have to jump back to our earlier legal panel. So which of the many people who could have responded are in fact on hook to respond and what kind of insight can you give us on the experience of having a mix of players responding to the information?

Gary Capistrant - Public Policy for American Telemedicine Association – Senior Director

Well, certainly there's a variety of ways of dealing with it and it is a learning process as the groups try and deal with it, and as they have the scale to standardize this more. Certainly, you know, those that have a lot of this, they have procedures for doing it. I mean it's much like in the in-person world, you know you go to a multi-physician practice and they have ways of exchanging that information to deal with it. So, in a way, the telehealth world should not be really different than the in-person world and there are always those kinds of coordinations.

I think one of the things with the technology now is that it's easier to track some of that interaction that it's usually in the form of some kind of message e-mail then it was 20 years ago in a completely analoged in-person kind of world. So, there's a value in that, also the value of having an archive and being able to see what that record is that it's not just an encounter about what that trend is, that those are all advantages that we have today to offset some of the disadvantages of that kind of flow.

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

Go ahead, Lacey.

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

Thank you. I was just going to respond that the challenge is there, as we went into a larger Beacon Community some of the preconceived ideas of who did what were definitely challenged. But the issue is no different if it's a patient-reported measure than if it is a clinical measure. When you're trying to reduce duplication in workflows or care it's no different than if you're going to duplicate a lab or are we going to request the information of a patient more than once and correspondingly how we react to those measures. So, if a patient goes from their primary care to their specialist and they're using a common lab value, irregardless of where it came to is no different than if they're using the same patient-reported measure where it came to. You have to have common agreement of workflow and rules in that setting no matter where the actual information came from.

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

Our experience in Project Health Design was quite different, in the five teams that are reported in the materials that you have we have five different clinical arrangements. And what was mentioned earlier today about the need to have a plan and an identified person to engage with the data is absolutely essential. In one of our teams at the University of Virginia and RTI they designated and redefined their care practice to put a triage team in place and it was a triage team that was the first point of contact.

In the…Project in Southern California the UC Irvine research staff worked with the clinical care staff of LA County and it was the care manager who had the first point of contact. Those were actually, although they're quite different there was a clear person to be engaged with.

In the project that was conducted at CMU in which patients homes, the homes of elders where instrumented with small sensors to know when a person was following their activities of daily living, taking medication or making coffee and when they skipped them the sensors fired, a report was generated and then it wasn't quite clear who it went to because all those patients saw different physicians, where living in a common care or a common residential facility but it was an apartment house, it wasn't a certified care facility. So, there was a social worker, occupational therapist engaged with them. In that case the team had to build a relationship with every single primary care person identified by the patient as the person who should respond to that information.

So, sometimes the care teams reorganized themselves, sometimes the teams built into an existing care process as in Southern California, and sometimes there was a point-to-point interaction driven by the patient's choice.

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

Yeah, Patti, you just reminded me it's not always…there is one thing, the caveat that goes with this, it's not just the collection of the measures and who is acting but also documenting who did act on that because as the team expands you need to know who did actually take action and what was the action.

David Lansky – Pacific Business Group on Health – President & CEO

Deven?

Deven McGraw – Center for Democracy & Technology – Director

So, I, my question actually follows along nicely, Patti, to the example that you just provided and of course since I'm familiar with the Project Health Design Grants I'm going to expect you to answer this question, but I'm also hoping that Gary and Lacey could have something to say about it too.

And I'm bringing back up for this panel to comment on a theme that I think has been present in our other panels today, which is that there is no one single definition of patient-generated data and figuring out sort of how we would approach this problem may not be at all able to be one-size-fits-all and so what does that mean for us in sort of constructing what…how Meaningful Use might advance this objective in Stage 3.

And I'm wondering if you have any thoughts about, given the very different ways that patient-generated data can manifest itself in the clinical workflow and the fact that Meaningful Use is typically, although not necessarily, on the measurement side tied to Meaningful Use of a certified EHR. What might be a way for us to consider providing a right set of incentives that Meaningful Use can provide in order to be able to stimulate this? Some form of patient-generated data, inclusion in clinical workflow in a meaningful and workable way?

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

Thank you for that simple question.

Deven McGraw – Center for Democracy & Technology – Director

I'm sorry, Patti.

Patricia Flatley Brennan, RN, PhD., FAAN – University of Wisconsin-Madison – Project Health Design National Program Director

The most important thing that the Meaningful Use Workgroup can do is to provide incentives and structure so that clinicians can document their chain of reasoning using patient-generated data. At this point in time we recognize the almost infeasibility and perhaps inappropriateness of direct entry of unfettered patient data into some aspect of one electronic health record when the patient may be seeing multiple clinicians.

We also recognize that the world is not ready for external third-party platforms like the carrot or HealthVault as part of the clinical healthcare information exchange, that may come, but in the short run what you can do is to provide assistance, incentives, and structures that clinicians have a way to systematically record the reasoning upon which they base their clinical judgment.

Resting clinical judgment on patient-generated data is no different than resting clinical judgment on any other health information. A clinician judiciously selects the kind of information that has to be brought in for the care of this particular person. The patient-generated data has many other purposes but in this particular instance to show Meaningful Use with Health IT it would be to find an easy way to effectively and safely document the clinician's use of that data.

Gary Capistrant - Public Policy for American Telemedicine Association – Senior Director

The Meaningful Use standards are obviously very important for what the vendors do and so creating even a 10% threshold in year one is more important than the 50% threshold in year three. So, you know, to move things forward so that at least that functionality is created is very key.

I think too sometimes we put too much emphasis on Meaningful Use, particularly in the innovative areas that I'm familiar with where very often it's what the innovation center at CMS wants is maybe more meaningful than what's in Meaningful Use. And so to recognize that as an opportunity to explore not just payment and service innovation but also what the data innovation is and when you have a small entity you can end up doing different things with different people to try and figure out what works, what is useful, how it deals with the workflow.

So, I think there is a lot of opportunity for both the Policy and Standards Committee to help along this very important area of chronic care and what we need to do to better address the data aspect of that.

Lacey Hart, MBA, PMP – Southeast Minnesota Beacon – Program Director

I echo Patti's reasoning of enabling the physicians to capture their chain of thought in order to provide quality care, taking our diabetic patients in our community we not only measure their hemoglobin A1c and their blood pressure, we also manage their fatigue, their quality of life, and their burden of care and it's those collective measures that we provide or the clinicians make decisions towards an appropriate care plan. And so, just making it so that the physicians or these systems have the ability to have that more holistic capture of their decisions towards the care model.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Russ?

Russell Leftwich, MD – Chief Medical Officer - Tennessee Office of eHealth Initiatives

Yeah, not a question but a comment, I think the discussion about who is responsible brings up the standards need for a clear minimum data set for the care team and what the role with respect to that patient is for each of those members, who is the first responder? Is the specialist really the de facto PCP because of the patient's complex disease, so it's a need we I think need sooner rather than later.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any other questions, comments? Okay, why don't we thank the panel for an informative discussion? Okay, we've, at least for the members of the Policy Committee we've been here in our chairs for 3 days, it is Friday, so we'll go around the table and not everybody has to say something, and maybe give some summarizing thoughts about the day and in particular what struck you as ways we can through policy labors and Meaningful Use Program help this along where appropriate. We can't go blazing ahead of where the market can take us, but what are the ways that we can provide for this kind of data and particularly for this kind of information to enter into patient care decision-making? Russ, I want to start with you?

Russell Leftwich, MD – Chief Medical Officer - Tennessee Office of eHealth Initiatives

Okay, I think there is one type of data that wasn't specifically mentioned that I think is important, maybe a value proposition for the providers as well as patients and provide better data and all that flows from that, and that is the question that the patient is asked face-to-face that they don't know the answer to but they can go home and find the answer and submit it and it may be an answer that they didn't have or it may be the right answer, and they would have given an answer that was not as accurate, and I think that's an important type of data that should be elucidated for the value proposition to the providers.

Another aspect and I don't want to discount at all what I think of patient-generated data because I think it's absolutely critical for care coordination, but I would suggest that we should catalog some of the potential unintended consequences so that we can plan to mitigate them and provide some guidance for implementers about these unintended consequences that are risks. One is data oversampling. If you have hypertension but your blood pressure has been normal every day for the past six months you probably don't need to take it every day, you're either pathologically obsessed with your blood pressure or you may be guilty of the fallacy that quality improvement has fallen into sometimes that measuring something improves it.

The second potential unintended consequence is, if to err is human, to make the data look like you want it to look is also human both for researchers and for patients and there are many studies that show that the data that patients transcribe tends to be skewed towards what they would hope it would be. And I think that's something that potentially creates two populations, if one population of patients has a device that directly uploads data while the other population is transcribing the data the quality of the data may be different.

And there is a related issue I think when a device or App is interposed between the patient and the EHR system that the data is going to, there's a significant risk when some of these devices are going to be unregulated yet maybe skewing or distorting the data, and I'm afraid we won't ever regulate all of them. I don't think the FDA is going to regulate Siri and, you know, Siri said that I didn't need to go to the ER for my crushing chest pain, so I think that there are issues with what can happen to the data between the patient and the EHR.

And the third I will mention is the risk of fascination with the technology that really doesn't have that much clinical or quality value. I specialize in taking care of asthma patients and I listened to the excitement about an inhaler with a GPS in it, you know, 95% of asthma patients are fine most of the time, most days and if they use their rescue inhaler three times a month, and they use it three times this afternoon they need to call me and you don't need a computer App to tell them that. So, there are certainly patients that we'll benefit from some of these great gadgets but it's not going to change the overall management of asthma, I think and I think there is that risk of being too fascinated with neat technology particularly in this patient-generated data area.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, Floyd?

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, I actually heard a couple of themes that I think are good to try to summarize. One came from Kate Goodrich, is knowing the source of the information, I think I heard that come up a number of times today and I kind of see it as not just knowing the source at the time you've received it so you know how to evaluate it but when you go back to look at and you're trending to know where that particular element came from makes a difference when you're trying trend data from different sources in the same graph or method.

I also heard some very significant things that can be done on patient-reported information, the issue of contraindications, whatever we call that is an analogy of contraindication, a problem driven by the patient so that it's managed and people know about it. How do we capture the information not necessarily on everybody but on those who need it to manage disease from devices without requiring that multiple additional steps and workflow from either patients or providers, but agree not in everybody.

But also a mechanism, the structure to be able to share information but that not all the information needs to be structured and I think Patti Brennan made a good case on that, although some patient-reported outcome to compare across providers say for value-based purchasing does need that structure but not all the information for care does and I think it's important to kind of think across that.

But a real kind of overriding, and I think it was Deven who said it, thing that came up for me was EHRs were designed more as a recording tool for what the clinician did and we're talking about it as a communication tool and is it the right device that we should be talking about? It's what HITECH has us working on, but we're making a paradigm shift for systems that are trying to change but are they the right things to do?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Charlene?

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

I think a lot of silver bullets came out today so I'm not going to put them all down, I'll let other people talk to them, but the one, the kind of conceptual piece in the morning that was really exciting hearing the panels and what was being done with patient generating data and then we have panel three which was the sobering panel in my view. So, let's get back to reality in terms of some of the barriers and the legal considerations, but the point that really came forward to me out of panel three was in areas where they're really using and studying the use of patient-generated data, there's a plan around it. There's a plan, there's a process, there's an intent, they've thought it through, they know how they're going to use it, they know how they're going to engage the patient, they know the expectation from the provider as well as from the patient.

And so that said to me, as I was looking forward to Meaningful Use I thought the suggestion certainly of having the ability to, you know, document the use or to actually show how you're using patient-generated data and be able to document how you're using that in your decision making to elevate that a little bit and say, okay let's link together the chronic disease and we've kind of talked about this even in Stage 2, some of the…or maybe some of our other Stage 3 stuff, you know, be able to demonstrate that you have a plan to manage patients with chronic disease using patient-generated data.

So, again, start to elevate it to make it such that we're motivating them to, if you will, do the right thing that will…again they'll have to think through protection and security and those types of things, as well as the ability to use patient-generated data potentially, you know, link it to clinical decision support and ultimately link it to perhaps some patient-generated measures. So, and I'll let others talk. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, quite a rich day. I think I've got three themes for myself coming out of this. So, in some ways it felt like there is a potential here for a really big paradigm shift and it was talked about in terms of the patient is really the individual that we're providing care for and his health is being monitored sort of like this continuous life and they're potentially collecting a lot of data about that life and the clinical interventions are really the isolated islands in time and that's really flipping the model because we've really been looking at provider based EHRs that we're going to connect and there will be continuity of care of some kind through those connections and they're sort of saying, well no we actually have it wrong.

The connector here is the individual in there and their life and we're plugging in at discrete points. So, I think there is sort of like a … and then how do we think about this? Because the examples we have are not very good. So, patient personal health records have not gotten much traction and no one really knows what to do with them. People are building huge data streams about their lives in isolated, you know, sort of the 1% in the tail folks are doing it today, but it's likely to pick up especially as analytics get better and it's not like, you know, I'm wearing this thing because I think it's cool to monitor my life, but hey, you know, when I use this thing and it controls my alarm clock, and I wake up refreshed, hey that's worth it for me so I'm going to start doing that, and maybe there's actually valuable data in there that a clinician might want to know, but it might just be valuable for me.

So, I think there's sort of a conceptual flip that could happen here. I think there are some other things that are really old problems, multiple data owners for different purposes. So, we have lots of people trying to coordinate care, they've got their own records, they're doing different things with them, how do we coordinate the team, how do we use the data, how do we do good provenance and that that's not new with patient data that's been around for a long time. And it's not new that patient data is the only thing that gets ignored, right? There are studies on lab results, abnormal labs come back and don't get acted on, right? That's not patient-generated data, the professionals asked for it, the data came back, came back to a known data feed, there's a process in place to act on it and it didn't get acted on. So it's not a new problem we're just potentially making it a bigger problem, which we don't have enough. We haven't done that yet, right? We don't have enough problems to make bigger.

So, maybe those are sort of my three pieces, that, you know, we could potentially flip the metaphor if we understood what to do with it in terms of the volume of data that we've got existing issues and multiple owners and data provenance, and that we have problems today of not acting on everything we know.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

George?

George Hripcsak – Columbia University

George Hripcsak. So, it was a very illuminating day. I think that I have a much better view of where we want to get to and I think Larry was describing that. Our job is to figure out how to get there, what's the next thing in Stage 3, so I'm still kind of struggling with how we divide the problem up and say here's what we're actually going to do next, whether we call it a taxonomy or just dividing up of the problem, so that's number one.

And the second thing I'll say is assuming that there's something we do and something we don't do on the don't do I like Patti's suggestion looking to see well what is it that you do even if you're not pulling in the data, well there's a commenting on the use of the data or something and I know I want to be careful we don't have any unintended consequences from that, but I want to think more in that direction too.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Marjorie?

Marjorie Rallins – American Medical Association – Director of Measures, Standards and Informatics for the Performance Improvement Division

So, Marjorie, Rallins, I live and breathe standards and I think one of the most compelling things I heard today that Floyd raised was not all information for care needs to be structured and standardized and I think that will be a challenge in moving forward. And the other thing for me was really moving forward and looking at the patient as the authoritative source regardless of the professional view of the provider. I think we need to contemplate that as we move forward. So, those are my two comments.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, John?

John Derr – Golden Living, LLC

Yeah, I think the main thing is that we have to…a lot of them said it different ways, but thinking longitudinally rather than episodic, whether it's different islands in the life of progress and quality of care, and then data has to be in real-time has all different kinds of connotations whether it's real-time when it's put in or real-time when it's happening, that if it has to be in there in many different senses because information has different layers, but the one that's real-time has to be there when action is to be taken.

A couple other things, I thought it was interesting that the data surveys that we do of patient-generated data has to be as important to the patient as it is to the physician that's using it to keep them engaged. One lady mentioned about the Maryland and removing data like taking to see how much is lead poisoning in the State of Maryland, I thought sometimes we think of transmitting data somebody mentioned receiving data, it's a two-way street and a lot of times we just think of it as going one way.

One was also tailoring the care communications to the level of patient activation. And I always have felt that you've got to get the individual involved in everything and they want to know what's happening to them. I think that's a culture change. I think in the old ways it is the physician always felt, well they don't want to know and Leslie and I had a long talk last night about telling the truth no matter what the truth is as a physician or as a caregiver. The patient deserves to know and really wants to know, at least the young person like that John at the end of the table he wants to know what's happening and the experience of knowing things about yourself.

And then in nursing homes we have one problem in the legal aspects and that's we've had a problem for years when we had software where you take nurses notes in a texting and nurses get very, very scared about putting down initial thoughts because they're afraid they're going to get in trouble. So, they wait and then they wait until it's too late and then it's bundled and then it's a generic person rather than the person, so we just have to somehow find a way that people can express themselves either the patient or the caregiver without getting in trouble by doing it.

Deven McGraw – Center for Democracy & Technology – Director

So, I think, and this is Deven, I asked my questions specifically and the question I asked of the last panel really helped to crystallize my thoughts, which is this is an incredibly exciting environment and maybe the most important thing we do is leave room for providers to be able do this in the way that makes sense to them and I think it's tied to the point that Patti and the others made in the last panel that when providers use patient-generated data in order to make a clinical decision they got to have a way to be able to document that, so that there is space for that, there is the capability of being able to do that there and maybe we can count on other incentives like payment reform initiatives, and accountable care organizations, value-based purchasing, outcome-based measurement to try to drive the incentives for providers who aren't currently sort of thinking about, wow how can I use the patient data from home to improve my outcomes to get them thinking in that direction rather than deciding that there are certain use cases that we're going to say, you know, you should really do this or do one of these, pick one from the menu type of model.

Now, that's, you know, again I have more in my head the model of patient-generated data that is like the Project Health Design Grants, because I'm obviously a huge fan and I think there's a lot of untapped potential there in that data that we've just been able to scratch the surface. And I certainly hope that while the low hanging fruit is the patient-generated data that is much more clearly clinical in nature like the blood glucose monitor readings and Hugo's readings from his heart, from his implant and I don't want to suggest it's not important because it is, but those…and we probably have some work to do to make those easy cases, but I hope we don't stop there.

Arthur Davidson – Denver Public Health Department

I was going to leave in just a minute, can I just put a few comments in?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yeah, go ahead.

Arthur Davidson – Denver Public Health Department

I thought that George's question about what are the topologies as something that our group really needs to consider, that, that was a good way for us to frame this up. I also thought that I think it was Gary on the last panel after the sobering panel as it was that defining what is a small threshold, I think we want people to take a step here. I don't think we want to go too far. The more we try to run at this point probably the more issues there will be about liability. So, I think those were the key things that I got out of today.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you.

W

…too, so I'll just pipe in for 2 seconds. I actually was going to say what Art said and I think it's sort of what I got to this morning, which is I think patient-generated data means different things to different people and this was a wake-up call for me for how broad and variable people are defining it and I think we need to think about how to chunk that down into smaller bits and prioritize and then, you know, figure out what's actionable early on and with an eye towards moving towards all of them overtime, but to try to be practical and realistic about it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, I started to feel overwhelmed when we had data, data everywhere and not a drop to drink, but it reminded me of the story in med school and training you have these attending rounds, and everybody is trying to second-guess what's the test we need to get and finally the attending speaks up and says, why don't we ask the patient? And the moral of the story being I think actually Nikolai and many of the patients know exactly out of the volume what they want you to know. So, potentially what we do is instead of worry about all this stuff just let them tell us what's important, which is pretty simple like a red highlight or something.

And then the making it useful, again Nikolai had this, which is maybe our translation of the certification criteria so can we do this contraindication? There are things that are contraindicated in me, so there's drugs, we know about that, but there are other things and we just never had a functionality and he suggested one of strapping it onto something we already have, so that was a lesson there.

And the final one was heard two compelling stories of where they actually are already using it, whether it was at Dartmouth or Partners, and they had one thing make it standard. So a nonproprietary standard so in fact you can make use of it otherwise it does become the data, data everywhere. But, at any rate, David?

David Lansky – Pacific Business Group on Health – President & CEO

Yeah, there are three things that stuck with me so far one is to your last point, Paul, how to scale it. We've got the Partners and Dartmouth's of the world, which are exceptional and how do we have the individual EHR meaningful user move down this path and I think the question for us is what can we do to stimulate that without being too prescriptive or taking too big of a step? And I think one way to do that, part of that will happen through payment reform and so on. But we should think about whether we can through quality measures or other tools that you get points for doing some things optionally and that they're fairly flexible boxes, really big boxes to get us pointing in. Let's think about for Stage 3 what can we put in place either under the criteria or the quality measures that incent most people to take a modest step forward.

But, the last thing I came up, from this last discussion what struck me is that we've been in a kind of a closed end process going to Stage 3, we had 1, then we had 2, then we have 3, 2 is a transition to 3 and then we're done. And what I think today reminded of, we might want to start thinking about Stage 3 as a transition to patient centered care and it's a place at which we begin to leave the planet of EHRs and move into the stratosphere of how do we…really of the big ecosystem, the universe of information about patient health that can be accessed in group and so on, because I think we've been pretty tethered because of the nature of the statute to the EHR construct and what we heard today is that's one important place where care is delivered and information is gathered, but from a patient longitudinal point of view it's not the end game. So, that will change my thinking about Stage 3 I think.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Eva?

Eva Powell – National Partnership for Women & Families

As I was trying to think about what I might share here in the end I started thinking about, well for Stage 3 what are the gaps, if you will, in terms of what we've done thus far in Meaningful Use. We've done a lot of great things and I think that was one thing for me that crystallized in the session both yesterday and today is that we have done some great things that have really tee'd up, put us in a really good spot for making even greater progress. Where I…and specific to the topic of patient-generated data I see that as being a critical piece of beginning to fill three gaps, as I see them anyway, in Meaningful Use and I use the term gap as we just haven't gotten there yet, not as a criticism.

The first is care coordination, that care coordination while the way we've structured it in our grid is that it's a fairly provider centered thing, we've got elements in the patient engagement criteria that compliment that, that care coordination cannot be done without the patient and family, and that as such we need a real-time data loop that gets at this concept that was shared earlier, it's not a care record but a care…oh, what was the term? A flow of care, something, I can't remember what it was called, but so that was one.

Then the other area is the area of quality measurement and the whole notion of somehow incorporating patient-generated data in a way that builds linkages to CDS and quality measurement and that was the conversation yesterday. And then finally and perhaps most importantly is the issue of disparities and that targeting some very specific data elements coming from patients and their families is probably a key point for really beginning to take some real active steps in addressing disparities through Meaningful Use in addition to the things we've already got there such as the collection of data, of demographic data. So, to that end what might be the initial steps, because I wholeheartedly agree with Deven's point and other points about leaving room and not being too prescriptive and it's clearly very early in this process and that we'll all be better off to let people tinker a little bit.

But the first is what I heard a lot today is that there needs to be some identified data that's useful for both patients and providers, I think that's a key to this puzzle is narrowing down what's actually actionable by both patients and providers, and in the spirit of leaving room a limited set of that, but I see that as actually something that we should probably be working on for Stage 3 is identifying what that limited set is, it maybe that in the process of doing that we figure out well maybe it's a little soon to do that, but I don't know I guess my feeling is that we may come up with at least something to give people something to work towards and that leads to the second step, which is the technical standards, which I won't belabor.

But, then finally I heard a lot about…it was interesting to me that I think it was Patti was talking about creating a framework for incorporating patient-generated data into practice and Deven said I think too that in the RWJ work that this was not a random process that there was a plan for incorporating this data which I think is a really, really important thing to bear in mind. But then I looked back at my notes from Nikolai's testimony and he said this provides a common frame for collaboration which I thought was really interesting to hear that from both the patient and providers, and again it points at that commonality so I think really there are very common desires and motivations here for patients and provider.

So, I don't know if that's a role for the Policy Committee to create this framework, maybe that is a little bit of structure we can build into whatever we do, this notion of having providers let us know how they're doing it, kind of the exchange of information and leave it open so that they can do whatever seems right. So, anyway that's a long-winded version of my thinking. But these were great panels.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

All right, Rebecca?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

I agree they were really good panels both today and yesterday and I don't want to reiterate what everybody else has said but I will reinforced the need to leverage what we can from other communities and I think that's very, very important. I think we had a little quick lunch discussion while we were chatting and we were talking about could we do a pilot and I don't know if we have that luxury or if we could go find some case studies or something about where we could borrow some things and learn from other experiences.

And I think also the third thing is how can we make sure that we look at how all these data streams need to converge and how many of them there are, and there's a whole effort out there that's paid for through contact research organizations to go do monitoring to make sure that what ends up going to the FDA is going to match what's at the site and I think, you know, we ought to be able to learn from some of that in terms of they have to make sure that every bit of data that's collected on this patient has, as I said before, an audit trail and also that you can make sure that where it landed it didn't get changed or if it did you can explain it.

So, I think that…you know, they're trying to deal with multiple streams of data as well. And so, I would just say to see what we can do from that and maybe see if there's something applicable that we could learn from in the near-term.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, Hugo?

Hugo Campos – Patient Advocate

Hi, so, one of the things that struck me today in this fascinating and very interesting day to me, and you see I don't have an MD or MPH, I'm sort of…I'm amongst you from my experience as a patient and somebody who deals with living with chronic disease, and a quest for information and data so that I can live my life in a better way, in a healthy way and hopefully a longer and healthier life.

So, what struck me interesting was to hear Nikolai's point that he made earlier today when he said to think of the patient as a health exchange of one and it really is an interesting concept, and an interesting idea in terms of really putting the patient in the driver's seat in many ways. And I think it's important for us to remember to not underestimate the patient after all, I mean look at us we're all patients at some point in our lives, we might develop a chronic disease and we're all perfectly capable of dealing with every aspect of our lives. We're expected to manage our careers; we're expected to manage our finances and every aspect of our lives. And so, healthcare should be something else that we should be able to manage.

I see my doctor for 30 minutes every year, once or twice a year for 15 to 20 minutes. So all the decisions are really left to myself as a patient to make every little decision that I make and it's really through…technology is not going to go anywhere. Technology is only going to get more ubiquitous and so we just need to figure out how we can close the loop in some of these gaps that are there, like for example in my case with patients with ICD's and pacemakers who have no access to the data, my doctor is not be expected to manage my chronic disease without access to information, so how can I be expected to do the same? So, in closing my…in a world in which we live with low-cost connectivity, we all have smart phones in our pockets, we should also find it sort of unacceptable for data to bypass the patient and I think it's sort of an interesting concept to keep in mind. So, I thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Anybody, Mary Jo, Josh, Michelle?

Josh Seidman – Office of the National Coordinator

One comment just to make because I think it came up in a number of the comments, in terms of direction and next steps for the committees, I think that clearly are things that you all have said you want to figure out how to give providers the ability to do stuff but not be overly prescriptive and I think that that's a good conversation for the Policy Committee and the Standards Committee's to have with each other because obviously the two committees are addressing two sides of the coin and thinking about what is it that it's important for providers to have access to from a technological stand-point when they buy a certified EHR for Stage 3 or beyond, but also, you know, ensuring that it's something that allows for the flexibility of providers.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's good, go ahead.

H. Westley Clark – Substance Abuse & Mental Health Services Administration

Yeah, Wes Clark, the whole purpose of this in part is to enhance the quality of care for patients and the patients then need to be the center of this as well. I agree with what Hugo was saying that if indeed we have mechanisms by which we can facilitate patient input then we treat the patient as opposed treating the chart and the chart is not the patient, and it's important for us to be able to move in that direction so the dialogue, the conversation and presentations we heard today move us in that direction, and the new technologies that are evolving even though they're not standardized at the moment are critical to that end, and if we're going to ultimately benefit the patient we need to hear from the patient. We can't just make the assumptions, it's not that clinicians, and I use the word clinicians because it's a much broader context now in the modern paradigm, because there are a host of nonphysician clinicians whose observations are essential to the well-being of the patient. So we can design these systems where we have good input and where patients and consumers can contribute to their own well-being.

And from a medical legal point of view we can also make sure that we can account for that information and I'm not malpractice lawyer but if indeed the software is designed to register the patient's content and it can be designed to also red flag certain types of content issues so that when the physician clinician shows up other clinicians may have made it clear that there seems to be a problem here and maybe you should pay attention to it.

I belong to Kaiser and was just at a surgeon's office and he pulled up the software, and the certain fields weren't obvious, and I asked him, well what about this procedure I just had, what about this and he had to hunt and search for it, it had nothing to do with patient input, the patient fortunately knew more about the software, the fielding than the practitioner and he ultimately found all of the information that "should have been there" but it wasn't as obvious.

So, there are these things that are, in terms of design, ergonomics that we have to worry about as we move in the right direction, but if we…and this represents an opportunity to make sure the patient's input, the consumer's input is made available and this is especially true for chronic care conditions, behavior health conditions and patient health behaviors. If the patient doesn't believe in the practitioner they don't go along with the program, if they don't go along with the program from a medical legal point of view you still may be liable but at least you won't get the outcome because, by the way you dismissed the patient's input. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you. Mary Jo?

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I'd like to make an observation as much for ONC and Jodi is not here right now, as for the committees, which is my take away is that this is clearly something that shouldn't be viewed through a single lens. What we've uncovered is how crosscutting this is and I think of other work streams that ONC has going on and most of which are going to come or are already before the committee, usability, clinical decision support, patient safety, this touches all of those. So, maybe another approach is to think of this as sort of a filter through which you view those other things as well and you infuse that other work with these issues so that you can get the synergy out of it.

I want to also mention that some of you may know that the UK right now has the equivalent of an RFI out on how to strengthen patient shared decision-making, you know, subtitled nothing about me without me, which is a phrase of course many in the US have been using and I'm not sure who it was, I think they said that some Brit had coined the term and I don't know, talk about provenance where it actually did originate, so…

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

…

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Okay, so I think that's very interesting and we had a consultation with our British colleagues yesterday about some joint efforts and this issue of patient-generated data was one of the areas that we're very interested in collaborating on. So there could be some follow up.

And my final point is, especially with regard to Paul's data, data everywhere and not a drop to drink is that data overload is certainly not unique to healthcare and one wonders how NSA filters the wheat from the chaff. Now, I'm sure they're not going to share their code with us or their algorithms, but I do think that learning from other sectors who have learned about decision-support and filtering of data might be of use.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Good, okay, well I think this has been a very productive…Charlene?

Charlene Underwood – Siemens Medical – Director, Government & Industry Affairs

I just want to add on a little bit to Mary Jo and what she is saying relative to patient safety. As a vendor you're sitting here and again this whole challenge of sifting the information to make it relevant to clinicians crosses the boundary of these systems starting to do medical intelligence and clinical decision support, and we start to think of regulation and FDA.

I know on the table is the need to start to create, if you will, a framework around the kind of work that we're doing. So, I just wanted to reinforce, because that's the kind…I'm sitting here thinking, you know, we can do this kind of stuff and on the other side I've got my compliance and legal people saying you're going cross that boundary and then we give the liability to the customer and then does it go to…you know how this chain goes.

So, I think it's really an important piece of the consideration that as we think through the kinds of capabilities and filtering, and surveillance we want, and clinical decision support we want EHRs to do we also think about it in the context of, you know, I hate to say a regulatory framework, but a framework that takes consideration of patient risk in the process and we think it through holistically.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes?

Eva Powell – National Partnership for Women & Families

Also in the spirit of Mary Jo's suggestion about how this is crosscutting and using this as a filter through which everything else is viewed, it strikes me that this is similar to the way we have tended to look at or at least Deven and I have tended look at privacy and security that to view this as an enabler of moving beyond some of the other barriers perhaps in that when you invite the patient into the fold, so to speak, that they are the ones that can help us overcome some of these issues that have been really tough nuts to crack and I'm not trying to suggest that it then becomes easy but the patient often can be the solution or part of the solution and that that's a big part of this as well.

Mary Jo Deering, Ph.D – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I can't help but add that in the intelligence world they know that the most valuable intelligence is what they call human intelligence. So, I think what this has taught us is that there is the human that is in fact probably the single most valuable source.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, I think as we go to Stage 3, as David was saying, Stage 2 was a transition to Stage 3, Stage 3 is where we're trying to break into the outcomes but even from 2009 we had placeholders for this area and we had really designated and I think we're sort of fulfilling that commitment and that vision as far as where we want to go. We still have to have, you know, the eye on the prize and our feet on the ground. We still have to know where we're standing, but as we go through preparing for Stage 3 recommendations we need to make sure that we accommodate things like this and I actually think we are having listened to some of the subgroups. Okay so speaking of consumer perspectives let's open it up to the public.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Paul. Operator can you please open the lines for public comment and while we're waiting if there is anyone in the room that would like to come up to the table to provide comment please do so.

Public Comment

Alan Merritt - Altarum Institute

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-2976, once you're connected press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Dean Brenner – Qualcomm, Incorporated

Hello everyone, my name is Dean Brenner and I'm from Qualcomm Incorporated. So, as we've heard throughout the day, Stage 3 should include the use of personal health data from remote patient monitoring technologies. Mobile health technologies are widely available and are proliferating rapidly. MHealth is a significant aspect of Health IT. ONC can further its goals to improve quality, safety, efficiency and reduce health disparities by considering the following.

One, incentivize the use of electronic self-management tools for patients with high priority health conditions. Two, offer the capability to upload and incorporate patient-generated data including home monitoring data into EHRs and include clinician workflow. Three, that this federal advisory committee evaluate the increasing role of mobile health devices in achieving Meaningful Use. Thank you.

Christopher Schultz – CHADIS – Chief Technology Officer

Good afternoon, Christopher Schultz, I'm the Chief Technology Officer for CHADIS; I work with Dr. Howard who provided testimony earlier. We have 15 million data points that we've collected over the last 10 years or so and we're forcing clinicians to come to us to retrieve that data. Please help us deliver those data to the clinicians that need them more conveniently. And to that end we would ask that you force the adoption of CCD as a part of Meaningful Use. Also, recognize that officially recognized templates are not sufficient.

Patti's assertion earlier that patients need to be able to define data as well as provided data is absolutely correct. CDA needs to allow for the inclusion of ad hoc patient-generated health data. Allow nonstandard or ad hoc data to be viewed using standards-based methods. The data provider of the ad hoc data could even provide the means to view that data using existing technologies such as extensible style sheet language templates.

Finally, CHADIS would welcome the opportunity to participate in this discussion moving forward. We applaud your efforts to facilitate Healthcare IT and want to support them. Thank you very much.

MacKenzie Robertson – Office of the National Coordinator

Is there any more public comment in the room? Operator, is there any public comment on the phone?

Alan Merritt - Altarum Institute

We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator

Okay, thanks, I'll turn it back over to you, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, and thank you all for participating vigorously in this past two-to-three days of hearings, meetings and so I bid you adieu until we see you next month, thank you.

Public Comment Received During the Meeting

1. What physicians do now is synthesize the patient's words into a succinct communication - how do we achieve that synthesis with all the data that patients might submit?
2. When a patient enters their data into the Electronic Medical Record, when is the provider legally obliged to make an entry as to their acknowledgment of the patient's entry (including date and time); and when is the provider obliged to make comments (clarification of facts, clarification of context, agreement of comment, proposed provider actions stemming from the patient's note) regarding the patient's entry. Also, is there an expectation that the patient be informed that the provider read and acted upon the patient's note. When provider notes are reviewed in the future, are patient notes (another source) supposed to be present along with provider notes? Are the consultants expected to have seen, read, and responded to the patient notes? Can the patient decide whom, among the care team, is allowed to see what notes (e.g. data segmentation)?